

PHARMAC ANNUAL PLAN

2004/05

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1 INTRODUCTION

1.1 Context for the Plan

PHARMAC's Objective

PHARMAC's overall objective, as outlined in section 47 of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) is:

to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.

This Plan outlines PHARMAC's objectives for the 2004/05 year.

1.1.1 PHARMAC's Statutory Functions

In accordance with section 48 of the NZPHD Act, the functions of PHARMAC are to perform the following within the amount of funding provided to it and in accordance with its Annual Plan and any directions given to it under section 65 of the NZPHD Act:

- a) to maintain and manage a Pharmaceutical Schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies;
- b) to manage incidental matters arising out of (a) including, in exceptional circumstances, providing for subsidies for the supply of pharmaceuticals not on the Pharmaceutical Schedule;
- c) to engage as it sees fit, but within its operational budget, in research to meet the objectives set out in section 47(a) of the NZPHD Act;
- d) to promote the responsible use of pharmaceuticals; and
- e) any other functions it is for the time being given by or under any enactment, or authorised to perform by the Minister of Health (the Minister) by written notice to the Board of PHARMAC after consultation with it.

As a result of an authorisation from the Minister in September 2001 under section 48(e) of the NZPHD Act 2000, PHARMAC is authorised to manage the purchasing of any or all pharmaceuticals, whether used either in a hospital or outside it, on behalf of District Health Boards (DHBs).

The purpose of this Plan is to set out PHARMAC's work plan for 2004/05 and inform stakeholders of how PHARMAC is going to put its functions into practice.

1.1.2 The New Zealand Pharmaceutical Market

The traditional multinational pharmaceutical companies continue to struggle to maintain their share of the taxpayer spend in New Zealand. A number of these established branded suppliers are facing diminishing business in New Zealand and in recent years have become more influenced by off-shore management. This sometimes makes it difficult for PHARMAC to progress proposals with those suppliers. At the same time, some of the established branded suppliers are generating new business in New Zealand and several new branded suppliers have entered the New Zealand market in the last year. The new players tend to be supplying high cost low volume pharmaceuticals so are unlikely to become major suppliers to the New Zealand market. PHARMAC continues to deal with a number of generic suppliers – both existing players in the New Zealand market and emerging suppliers.

Key factors which are influencing the New Zealand market are:

- patents expiry leading to loss of market or downward pressure on prices;
- PHARMAC resisting investment in marginal technology (eg Alzheimer's treatments, Cox 2 Inhibitors);
- PHARMAC tenders; and
- a lack of new products able to be brought to market.

The role of the Researched Medicines Industry (RMI) has diminished in recent years. However, the recent change in Chair, and a change in political and media strategy indicate that PHARMAC will continue to face pressure from industry representatives.

1.2 Policy Expectations

The New Zealand Health Strategy provides the framework in which PHARMAC works and determines our priorities. The Primary Care Strategy emphasises the importance of a strong primary care system within this framework. Key tenets of these strategies are community involvement and participation; health promotion; and preventative care and education through the use of good information. The documents acknowledge the special relationship between Maori and the Crown under the Treaty of Waitangi, particularly their need to be involved with Maori health care.

The New Zealand Health Strategy articulates the Government's expectation that the health and disability support sector will work towards achieving the following priorities:

- very good health and independence for all New Zealanders, and reduced disparities in health and disability outcomes;
- access for all New Zealanders to an acceptable range of health care and disability support services, regardless of ability to pay; and
- a high-performing system in which people have confidence.

PHARMAC's activities contribute to these priorities in a number of ways:

- working with Maori as Treaty partners with the Crown to address issues relating to pharmaceuticals that affect Maori as outlined in PHARMAC's Maori Responsiveness Strategy;
- PHARMAC recognises that pharmaceuticals are instrumental in improving the health and well-being of New Zealanders throughout their lives;
- access to subsidised pharmaceuticals is part of ensuring equitable access for all New Zealanders to a comprehensive range of health services, regardless of ability to pay;
- PHARMAC's evaluation of new drug technologies and investment in superior technologies contributes to a high-performing system;
- PHARMAC's efforts to obtain the optimum value from pharmaceutical funding assist with the process of meeting need within the funds available;
- consulting with PHARMAC's Consumer Advisory Committee as representatives of patients and to provide input from health consumers' points of view on PHARMAC's processes;
- PHARMAC's encouragement of the responsible and cost-effective use of pharmaceuticals through its activities to Promote the Responsible Use of Pharmaceuticals, contributes to the health of New Zealanders and enhances the quality of healthcare provided; and
- PHARMAC's hospital strategy encourages co-operative purchasing arrangements amongst DHBs.

The 13 population objectives, outlined in the New Zealand Health Strategy are:

- reduction in smoking;
- improved nutrition;
- reduction in obesity;
- increase the level of physical activity;
- reduction in the incidence of suicide and suicide attempts;
- minimising the harm caused by alcohol and illicit and other drug use to both individuals and the community;
- reduction in the incidence and impact of cancer;
- reduction in the incidence and impact of cardiovascular disease;
- reduction in the incidence and impact of diabetes;
- improve oral health;
- reduce violence in interpersonal relationships, families, schools and communities;
- improving the health status of people with severe mental illness; and
- ensure access to appropriate child health care services including well child and family health care and immunisation.

The Primary Health Care Strategy also has priorities which are aligned with PHARMAC's. In terms of the six priorities outlined in this strategy, PHARMAC can contribute towards:

- working with local communities and enrolled populations;
- identifying and removing health inequalities;
- offering access to comprehensive services to improve, maintain and restore people's health across service areas;
- co-ordinating care across service areas; and
- continuously improving quality using good information.

As part of its Maori Responsiveness Strategy, which was launched in September 2002, PHARMAC is implementing six key strategies:

- incorporate Maori strategic priorities;
- improve human resources;
- improve ethnicity data collection and analysis;
- improve our performance in negotiating with suppliers and assessing new drug applications;
- improve our performance in informing Maori about available subsidised medicines; and
- improve Maori representation and participation.

1.2.1 Incorporating Government Priorities into PHARMAC's Activities in 2004/05

PHARMAC contributes to the above Government strategies both directly and indirectly and they have guided us in setting our work programme for 2004/05. DHBs and PHARMAC will work together on initiatives to improve access to pharmaceuticals which will impact upon these population objectives.

PHARMAC takes government priorities into account when developing its work programme and making decisions concerning the Pharmaceutical Schedule. The Pharmaceutical Schedule determines eligibility for access to subsidised pharmaceuticals and PHARMAC's management of the Schedule involves:

- medical and economic assessment of new drugs;
- reviews of currently subsidised pharmaceuticals;
- negotiation with pharmaceutical suppliers to manage the financial risks from funding medicines; and
- promulgation of the Schedule.

PHARMAC updates the Pharmaceutical Schedule at regular intervals, taking into account, where applicable, the following decision criteria as stated in our Operating Policies and Procedures:

- the health needs of all eligible people within New Zealand;

- the particular health needs of Maori and Pacific peoples;
- the availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
- the clinical benefits and risks of pharmaceuticals;
- the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
- the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule;
- the direct cost to health service users;
- the Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Crown Funding Agreement, or elsewhere; and
- such other matters as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other matters" into account.

PHARMAC incorporates Government priority areas in the process of applying these criteria. In the first instance, PHARMAC relates all its activities to its legislative objective of securing for those in need of pharmaceuticals "the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

PHARMAC will support its decisions by the following strategies which aim to improve the value of pharmaceutical expenditure:

- independent advice from the Pharmacology and Therapeutics Advisory Committee (PTAC) to PHARMAC on pharmaceuticals and their benefits;
- information received from PHARMAC's Consumer Advisory Committee (CAC);
- assessment of significant new investments, using the principles outlined in PHARMAC's Prescription for Pharmaco-Economic Analysis, as updated from time to time;
- cost utility analysis, used to assess some current investments of poor value, with subsequent dis-investment, where appropriate;
- consulting on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups, or individuals that, in the view of PHARMAC, may be affected by decisions on those matters, (which may according to the circumstances include DHBs, pharmaceutical suppliers, PTAC, health professionals, CAC, community or patient groups, Maori, Pacific Peoples and other groups); and
- take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the Pharmaceutical Schedule.

PHARMAC will use a number of strategies for negotiating with drug companies to achieve the set pharmaceutical expenditure goals. PHARMAC's standard "tool kit" for managing the pharmaceutical budget includes:

- reference pricing;
- capped expenditure contracts;
- rebate arrangements;
- price/volume arrangements;
- package deals; and
- tendering for sole supply.

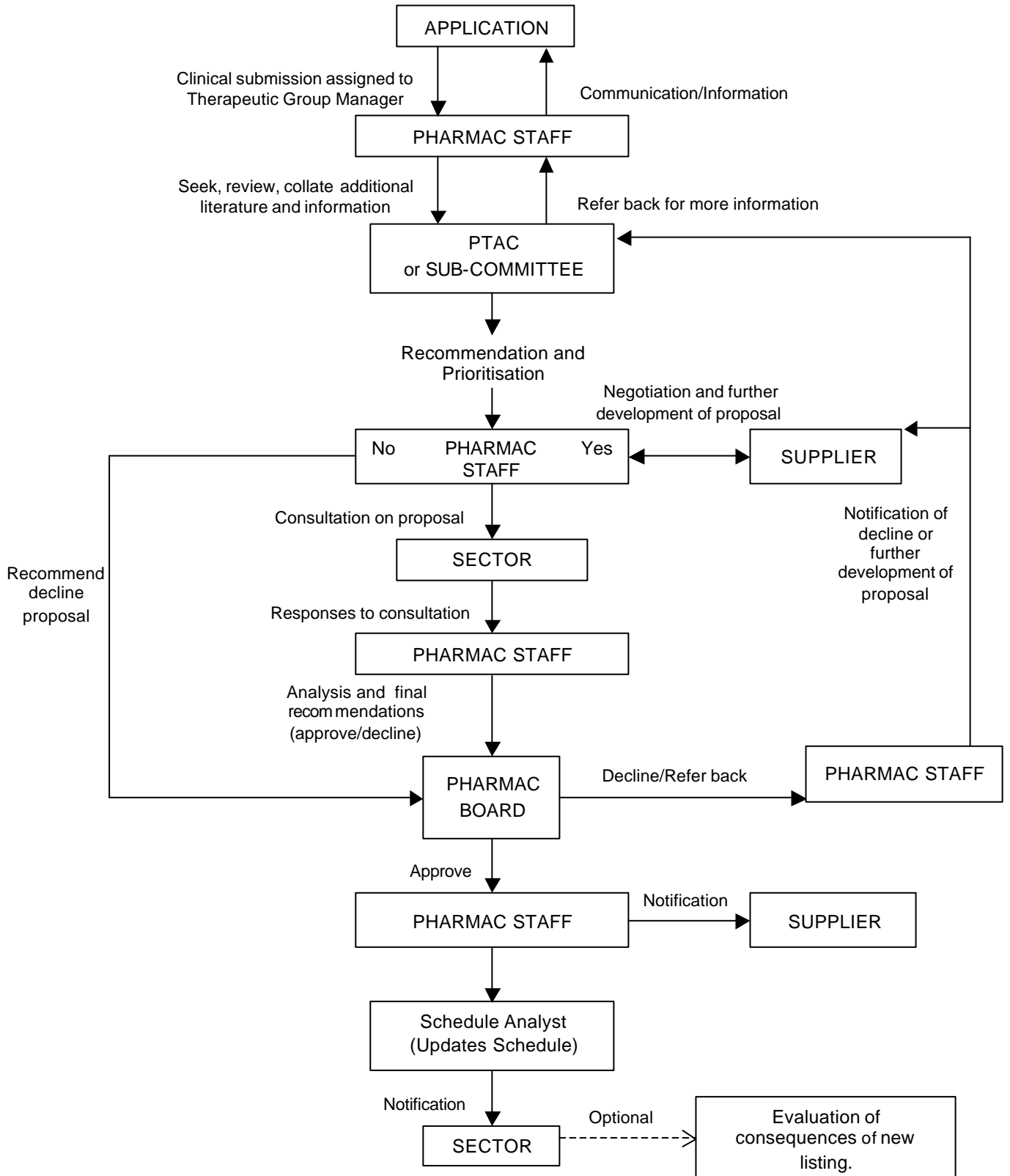
PHARMAC's ability to introduce new medications is dependent on funding. If a proposal indicates that there will be overall savings to health sector budgets, it is immediately recommended to PHARMAC's Board (or the Chief Executive under delegated authority). Proposals that result in changes to access criteria can result in savings if, for example, a proposal to list a new product will result in it being substituted for another more expensive medicine already being subsidised.

If it appears a proposal will result in increased costs to health sector budgets and funds are available, listing is recommended if it meets PHARMAC's Decision Criteria. Cost effectiveness analysis is only a guide for decision makers, not a substitute for decision-making.

If it is likely the proposal will result in increased costs to health sector budgets and funds are not available, the proposal is wait-listed. When funding becomes available the proposal most likely to receive funding will be that which the Board considers most appropriate taking into account the Decision Criteria.

The Decision Criteria (paragraph H) specifically involves consideration of Government priorities as part of the approval process for proposals. Conflicts between objectives are resolved by recognising that PHARMAC's legislative objective has precedence. The decision making process is outlined in the flow diagram on the next page.

1.2.2 Current PHARMAC Decision Making Process for the Subsidised Listing of Pharmaceuticals for Community Use.



Note: This diagram provides a simplified, indicative guide to the process that PHARMAC will usually follow when listing a pharmaceutical on the Schedule. PHARMAC is not bound to follow the process set out in the diagram and may vary this process or adopt a different process where appropriate.

1.3 PHARMAC's Organisational Structure

PHARMAC is a Crown entity established under the New Zealand Public Health and Disability Act 2000.

The Minister of Health is accountable to Parliament for the overall performance of PHARMAC. The role of the Minister in relation to the performance of PHARMAC is set out in the Crown Funding Agreement between PHARMAC and the Crown. The Minister is not responsible for the day-to-day activities of PHARMAC. That is the responsibility of the PHARMAC Board.

All decisions relating to the operation of PHARMAC are made by or under the authority of the Board. The Board has all powers necessary for the governance and management of PHARMAC. The Board is to ensure that PHARMAC delivers the Outputs under the Crown Funding Agreement; achieves the financial performance and provides the reports specified in the Crown Funding Agreement; and complies with all other requirements associated with its objectives, powers, obligations and functions under the NZPHD Act. The Board is also responsible for agreeing PHARMAC's accountability documents with the Minister.

PHARMAC's Board consists of up to six members with a range of backgrounds, representing a diverse range of skills and professional knowledge from both the public and private sector. Members of the Board are appointed by the Minister. Current members of the PHARMAC Board are Richard Waddel (Chairman), Professor Gregor Coster, Karen Guilliland, Helmut Modlik, David Moore and Adrienne von Tunzelmann.

The Board makes the final decisions on subsidy levels and prescribing criteria and conditions with independent advice from medical experts on the Pharmacology and Therapeutics Advisory Committee (PTAC) and advice from PTAC's specialist sub committees and PHARMAC's managers and analysts.

Current members of PTAC are Carl Burgess (Chair), Ian Hosford, Sisira Jayathissa, Howard Jones, Peter Jones, Jim Lello, Peter Pillans, Anthony Ruakere, Tom Thompson and Paul Tomlinson. Members of PTAC are appointed by the Director-General of Health following a recommendation being made by the PHARMAC Board.

There are also several other committees providing advice to PHARMAC. These include the Hospital Advisory Committee (HPAC) and the Consumer Advisory Committee (CAC).

2 STRATEGIC PRIORITIES

This year marks the fourth year of PHARMAC's operations as a stand-alone Crown Entity. For the first time PHARMAC has a three year funding path. This will enable PHARMAC to concentrate on increasing both the range of pharmaceuticals available and access to them. This will in turn assist companies supplying subsidised pharmaceuticals to plan in out-years. In order to continue to achieve the successes that PHARMAC has achieved in the past PHARMAC must:

- focus on the activities of gaining value from investment decisions and maximising health outcomes from pharmaceutical treatment;
- continue to develop strong relationships with its stakeholders; and
- continue to promote the responsible use of pharmaceuticals as a means of managing pharmaceutical expenditure and use.

PHARMAC's Board is committed to ensuring that the strategic priorities identified below are achieved and that PHARMAC is well positioned to meet future challenges. The Board has developed a Delegation Policy which enables the day-to-day operation of the organisation to be managed by the management team. Only issues which represent legal or political risk, exceed certain financial limits or are of strategic importance in the opinion of the Chief Executive, will be put before the Board. The Board will set the direction for PHARMAC and focus on the development of strategic relationships.

In setting these strategic priorities, PHARMAC has held strategy workshops with the Board, which were attended by representatives from certain of PHARMAC's stakeholders, and planning sessions with staff. Staff continue to be involved in identifying opportunities for additional savings and priorities for listing new pharmaceuticals; developing Demand Side activities which promote the responsible use of pharmaceuticals (including the utilisation of pharmaceuticals by Maori); responding to sector changes; and improving relationship management. PHARMAC is also committed to ensuring that it has the internal capacity to ensure that these priorities are achieved. As a result of these evaluations PHARMAC has reaffirmed the vision and values outlined below.

2.1 Vision and Values

2.1.1 Vision

PHARMAC's vision is to provide best value medicines for all New Zealanders.

2.1.2 Values

Our values drive our actions and determine the organisation for which we strive. We will consistently seek to achieve the following values in all areas of our work:

- We act professionally, creating positive stakeholder impressions.
- We listen to our stakeholders and acknowledge their point of view.

- We use our job knowledge and share information so that we resolve enquiries and issues effectively.
- We manage expectations so that stakeholders understand what can be achieved, and when.
- We meet the needs of other staff so that PHARMAC achieves its goals.
- We value: working together for common goals, dedication and hard work to get the job done, sharing information and seeking the opinions of others, staff support and evidence-based decision making.
- We don't value: people dealing with their differences or stresses using displays of anger or disrespectful behaviour/conduct that is disruptive to PHARMAC.

2.2 Strategic Priorities

In preparing its accountability documents for the 2004/05 financial year PHARMAC has undertaken a review of the Strategic Priorities which will guide its business activities over the following three-year period. As a result of this review, PHARMAC has revised its Strategic Priorities. While the new Strategic Priorities are consistent with those PHARMAC has relied on in the past, they reflect the development of PHARMAC's core activities and its planned future direction. Strategic Priority 7 reflects new initiatives which are a short term priority but which are ultimately expected to either form part of PHARMAC's core activities or to fall away. PHARMAC expects that this priority will change annually over the three year period envisaged by this Annual Plan.

PHARMAC's Strategic Priorities for 2004/05 are outlined below:

Strategic Priority 1: Comprehensive management of pharmaceutical expenditure and use

PHARMAC will ensure that the Pharmaceutical Schedule is managed in a manner that ensures that treatments are appropriately prioritised and listed, and that maximises health outcomes from within the funding available. PHARMAC will also engage in strategies to promote the cost effective, responsible use and prescribing of pharmaceuticals.

Strategic priority 2: National Hospital Pharmaceutical Strategy

Following the successful implementation and review of the National Hospital Pharmaceutical Strategy, PHARMAC will further develop and implement the Strategy to assist DHBs with the management of expenditure on hospital pharmaceuticals.

Strategic Priority 3: Working with DHBs

Building on the closer co-operation which has been achieved between PHARMAC and DHBs, PHARMAC will focus on improving information sharing and risk management and on developing and implementing specific initiatives that benefit DHBs.

Strategic Priority 4: Ensuring all New Zealanders have similar access to subsidised pharmaceuticals

PHARMAC will engage in initiatives to promote the appropriate use of pharmaceuticals by disadvantaged populations, including Maori, to improve health outcomes and health status and ensure utilisation is similar across all groups of New Zealanders.

Strategic Priority 5: Improving Relationships with Stakeholders

PHARMAC will develop its relationships with stakeholders through regular meetings and a clear communications strategy aimed at achieving a better understanding of PHARMAC's objectives in the wider public arena. Key relationships include the Minister, the Ministry of Health, all politicians, other government agencies, clinicians, pharmacists, patients and their representative groups, Maori, and the pharmaceutical industry.

Strategic Priority 6: Developing PHARMAC's internal capacity

PHARMAC will ensure that it has the capability to meet its business objectives through the recruitment of staff with appropriate skills, experience and knowledge and the provision of an attractive working environment through demonstrating the value it places on staff.

Strategic Priority 7: New initiatives to assist DHBs

PHARMAC will extend its operational activity to include new initiatives that assist DHBs. In 2004/05, PHARMAC will procure the influenza vaccine, and will systematically take over the management of the pharmaceutical cancer treatments budget (the "Cancer Basket"). PHARMAC will also develop further initiatives, in conjunction with DHBs.

2.3 Achieving Strategic Priorities

PHARMAC's aim in 2004/05 is to focus on:

- continuing to manage the Pharmaceutical Schedule effectively by listing products that will help achieve the objectives outlined in the New Zealand Health Strategy (Strategic Priority 1);
- improving PHARMAC's work in promoting the responsible use of pharmaceuticals by focussing on projects with measurable outputs and/or outcomes over the medium term. (Strategic Priority 1);
- developing mechanisms with DHBs for on-going funding of Demand Side Campaigns (Strategic Priority 1);
- continuing to seek ongoing benefits through nation-wide hospital pharmaceutical purchasing and looking for synergies between the community and hospital pharmaceutical sectors (Strategic Priority 2);

- developing increasingly closer working relationships with DHBs through improved information sharing and risk management (Strategic Priority 3);
- contributing to improvements in the health status of all New Zealanders by helping to ensure that all New Zealanders have similar access to subsidised pharmaceuticals (Strategic Priority 4);
- working to identify representative groups which will be impacted by PHARMAC activities and decisions and communicating with those groups prior to significant decisions where possible (Strategic Priority 5);
- reviewing internal structures and skill sets to ensure that PHARMAC is best placed to achieve its aims in promoting the responsible use of pharmaceuticals (Strategic Priority 6);
- taking steps to procure the influenza vaccine for use in the community and progressing the consideration of the transfer to PHARMAC of management of the Cancer Basket (Strategic Priority 7); and
- developing further new initiatives with DHBs – to support them in achieving their objectives (Strategic Priority 7).

As well as the key strategies outlined above, PHARMAC's future direction will focus on developing strategic alliances with others in the sector and maximising core competencies such as analysis and assessment tools which could be used as a blueprint for other areas of the health sector. These activities will ensure that PHARMAC continues to achieve excellent results in managing New Zealand's pharmaceutical budget while building relationships across the sector and offering its expertise to improve health and fiscal outcomes for New Zealand.

PHARMAC's plans for each of these strategic priority areas are set out in more detail below. In planning for these strategic priorities, PHARMAC has made a distinction between those priorities which encompass funding responsibilities (Strategic Priorities 1 and 2) and those priorities which are intended to enable PHARMAC's performance of its core statutory function (Strategic Priorities 3, 4, 5 and 6). Strategic Priority 7 is more closely aligned with PHARMAC's funding responsibilities. However, this could change depending on the nature of initiatives which PHARMAC and DHBs decide to work together on. For the purposes of this Annual Plan, PHARMAC has dealt with Strategic Priority 7 as a funding responsibility. PHARMAC's plans in relation to funding responsibilities are set out in Section 3.1 below. Planning in relation to priorities which enable optimum performance are set out in Section 3.2 below.

This distinction has also been used by PHARMAC in setting its performance targets for the year. Strategic Priorities 1, 2 and 7 relate to purchase objectives which are set out in Section 6.2.1 below. Strategic Priorities 3, 4, 5 and 6 relate to ownership performance objectives which are set out in Section 6.2.2 below.

3 PHARMAC PERFORMANCE

3.1 Outline of Funding Responsibilities for 2004/05

Outlined below is an overview of recent trends in pharmaceutical expenditure. Following this section detail is provided on the focus for the 2004/05 year.

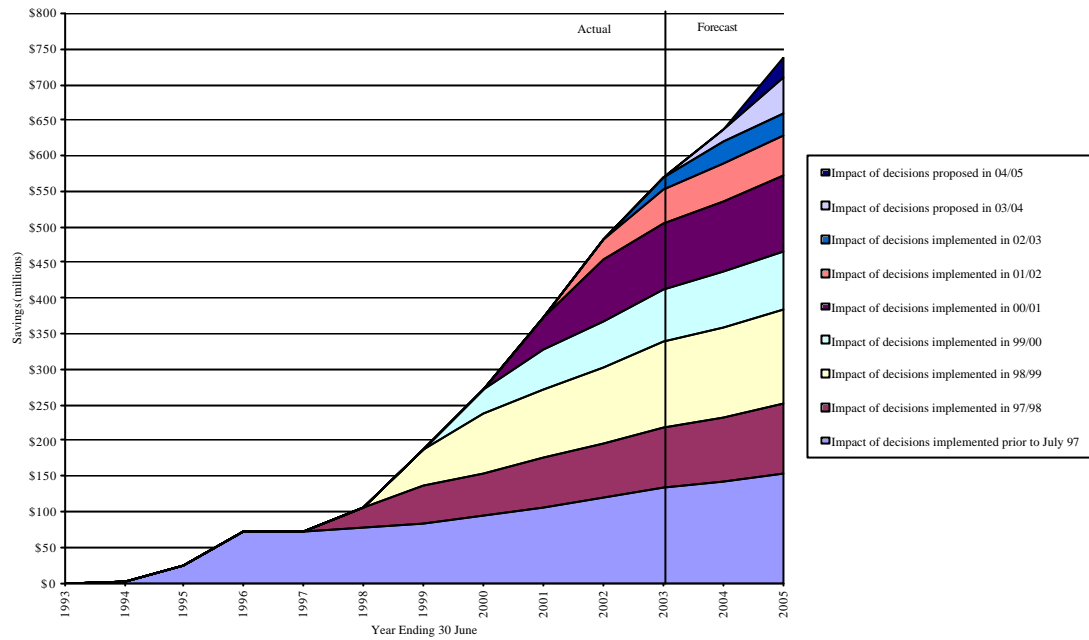
(a) Expenditure trends by therapeutic group

	<i>Jun-00</i>	<i>Jun-01</i>	<i>Jun-02</i>	<i>Jun-03</i>
Alimentary Tract and Metabolism	\$91.67	\$100.57	\$104.57	\$114.04
Blood and Blood Forming Organs	\$47.15	\$57.27	\$53.86	\$59.03
Cardiovascular System	\$74.57	\$68.69	\$58.75	\$60.82
Dermatologicals	\$21.51	\$21.25	\$21.35	\$19.54
Genito-Urinary System	\$13.86	\$13.66	\$13.40	\$13.00
Hormone Preparations - Systemic excluding Contraceptive Hormones	\$25.37	\$28.10	\$29.67	\$28.49
Infections - Agents for Systemic Use	\$39.30	\$33.91	\$32.35	\$32.80
Musculo-Skeletal System	\$12.00	\$7.91	\$7.05	\$9.11
Nervous System	\$100.90	\$105.01	\$117.46	\$129.54
Oncology Agents and Immunosuppressants	\$16.51	\$20.42	\$21.57	\$23.92
Respiratory System and Allergies	\$68.78	\$62.32	\$60.88	\$60.34
Sensory Organs	\$6.58	\$7.04	\$7.48	\$8.03
Special Foods	\$6.47	\$7.65	\$8.41	\$9.17
Extemporaneously Compounded Preparations and Galenicals	\$0.02	\$0.01	\$0.01	\$0.01
Unknown	\$1.49	\$0.85	\$0.39	\$0.54
Total	\$526.17	\$534.65	\$537.20	\$568.37

Note:

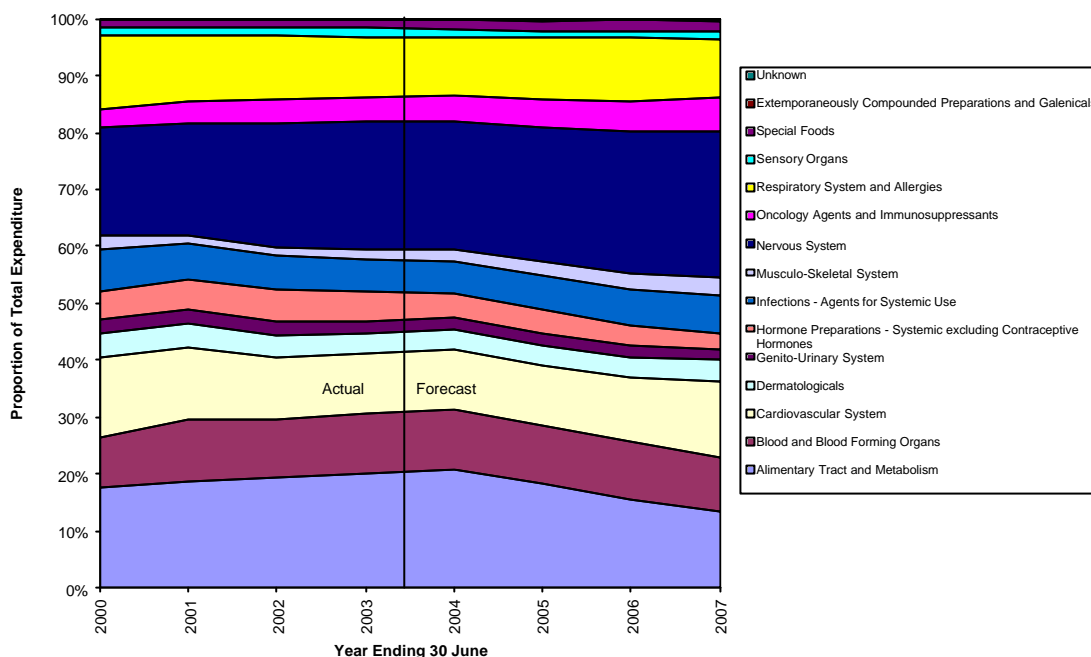
1. Expenditure is shown in millions of dollars.
2. Expenditure excludes savings from rebates .

(b) Cumulative savings from past subsidy reductions



This graph shows how decisions implemented in any particular year continue to produce savings in the out-years such that the value of total savings grows over time. The graph indicates that without the subsidy reductions implemented by PHARMAC, spending on community pharmaceuticals would be at least \$425 million higher than its current level (which is around \$505 million). It also indicates that over its 10 year history, PHARMAC has saved, in constant dollars, around \$3.2 billion (the total of columns up to 2003 in the chart above adjusted for inflation). The graph excludes savings PHARMAC has generated by either not listing a new product or listing new products with targeting criteria. The savings have been achieved at a total operating cost to the taxpayer of less than \$40 million.

(c) Therapeutic group expenditure as a percentage of total expenditure



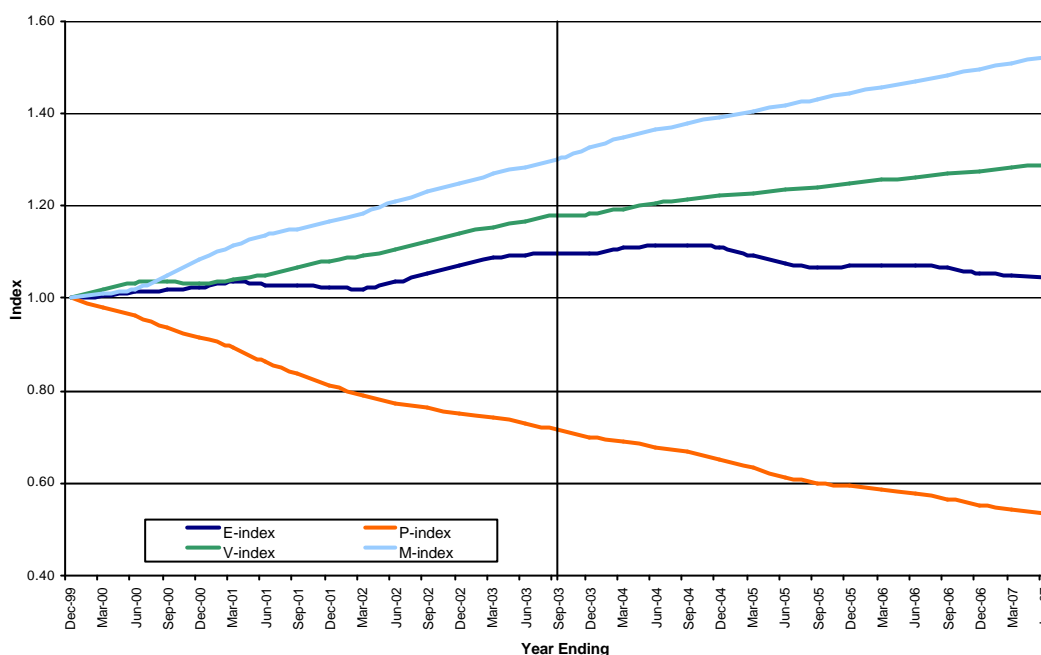
Note: values for 2004, 2005, 2006 and 2007 are forecasts and exclude new investments, savings from tenders and savings from rebates.

As a result of the savings opportunities taken by PHARMAC and the new investments made, each therapeutic group's share of total pharmaceutical expenditure has changed over time, as shown by the graph above.

Also shown is how these shares are anticipated to change over the next three years. These shifts in share are, to a large extent, opportunistic but deliberate as opposed to planned and deliberate. Exceptions to this include the large investment in newer anti-psychotic medicines and the planned movement of funds from the treatment of raised blood pressure to the treatment of dyslipidaemia. To a great extent they represent what proportion of the therapeutic group is made up of off-patent and/or me-too drugs relative to on-patent drugs over time.

It should be noted however, that this overall picture of the market is insufficient for determining which drugs/therapeutic groups offer the greatest value for money and therefore, which ones should receive extra funding and which a cut-back.

(d) Price, volume and mix trends



Note: the subsidy reductions from December 2005 of the forecast are predicted as an extrapolation of the P-index and not as an estimate of the impact of forecast transactions.

The PVM graph indicates that underlying annual growth in spending due to volume growth is around 4%, that annual growth due to mix is around 7%, and that annual growth due to prices is around -9%. If the fall in prices stopped, spending would be expected to grow at around 11% a year (assuming no new investments).

(e) Potential impact of Primary Health Organisations (PHOs) and government access policies

The government is implementing new policies and adjusting others to increase access to health care among lower socio-economic groups. These policy changes include the establishment of PHOs which, among other things, will over time provide many patients with free access to health practitioners, lead to changes in co-payment levels subsidies for 16 to 17 year olds and the elderly (over 65), and involve changes in GMS payments for 'High Use Health Users'. All of these policies are anticipated to increase demand for referred services including pharmaceuticals.

PHARMAC has allowed for \$31 million in increased pharmaceutical utilisation resulting from PHOs reducing the barriers to accessing primary care. This is based on Ministry of Health forecasts. PHARMAC will continue to monitor the impact of PHOs on pharmaceutical volumes and as PHOs develop, will use this information to strengthen the robustness of pharmaceutical expenditure forecasting.

3.1.1 Supply Side Initiatives for 2004/05

➤ Total therapeutic group management – linking supply and demand

PHARMAC's success in managing the community pharmaceutical budget has been predominantly as the result of Supply Side team initiatives managing price and to some degree the volume and mix components of pharmaceutical expenditure. Volume has been impacted by targeting tools such as the Special Authority mechanism and mix has been impacted by reference pricing and tendering.

In 1997 PHARMAC recognised a need to specifically target the management of volume and mix (i.e. the management of the demand for pharmaceuticals) and developed the Demand Side management function, which was written into legislation in the NZPHD Act.

To ensure the total management of therapeutic group expenditure, PHARMAC Supply and Demand Side teams are working together. The seamless management of therapeutic group supply and demand issues is an important internal focus for PHARMAC.

The key strategic approaches that the Supply Side team adopt to manage the pharmaceutical budget are:

- exploiting market opportunities to reduce the unit cost of pharmaceuticals, so that DHBs obtain better value on existing medicines and so that new investments can be funded;
- listing pharmaceuticals that are assessed as offering value for money within the budget that is available, so that health outcomes for the New Zealand population are improved;
- monitoring and managing our supplier contracts, so that DHBs receive the full benefit of our supply agreements;
- managing and enhancing our relationships with all our stakeholders, so that our stakeholders perceive PHARMAC as an effective and valuable organisation.

➤ Utilising market opportunities for reductions in unit subsidy cost

PHARMAC has secured lower prices for a number of key products in the last 12-18 months. This leaves only a couple of key products coming off patent in the next year for which new prices need to be negotiated using PHARMAC's 'tool kit' (as set out in section 1.2.1 above) in an effort to get the best value for DHBs' investment in medicines. Savings activities will therefore be focused on obtaining the most value from the tender for 2004/05 and, to a lesser degree, disinvestment in areas of low health benefit.

➤ Listing pharmaceuticals that are assessed as offering value for money within the available budget

This year it appears likely that PHARMAC will be able to make significant new investments in medicines. The investment opportunities that we have identified for 2004/05 fall within the following therapeutic groups:

- Respiratory
- Oncology and Immunosuppression
- Analgesia
- Mental Health
- Infections
- Diabetes
- Blood and blood forming
- Dermatology
- Musculoskeletal

The challenge will be completing assessments for new pharmaceuticals and securing acceptable commercial arrangements in time for investments to be made within the financial year. Any delays experienced with implementation of targeting mechanisms could also limit PHARMAC's ability to invest in new medicines.

➤ ***Focus on New Zealand Health Strategy priorities***

If funding is available, among the possible new investments highlighted above, a number would assist in the Government's aims as identified in the New Zealand Health Strategy. In particular, there are new medicines to improve the treatment of diabetes and cancer and to assist in the management of people with schizophrenia and depression.

Over the last two and a half years, PHARMAC has worked extensively in collaboration with the Ministry and its specialist advisors on cancer issues to develop a long-term solution to the issues of national equity of access to pharmaceutical cancer treatments, which prompted a Ministerial direction to DHBs in October 2001. As a consequence, PHARMAC now provides resources and expertise in prioritisation mechanisms and commercial negotiations in relation to pharmaceuticals via a national assessment process for pharmaceutical cancer treatments and will this year progress initiatives to address budgetary issues. Continued involvement with the Ministry, DHBs and cancer treatment specialists on related issues signals PHARMAC's commitment to assisting with relevant aspects of the Ministry's Cancer Control Strategy. Ongoing collaboration with these groups will also be required to ensure that those pharmaceutical cancer treatments used in DHB Hospitals are prioritised and funded, where appropriate, as quickly as possible. PHARMAC's work in this area is also illustrated by Strategic Priority 7 which recognises the work being undertaken by PHARMAC in connection with the possible transfer to PHARMAC of the management of the Cancer Basket.

➤ ***Monitoring and managing our supplier contracts***

We will ensure that all benefits due to DHBs (price reductions, rebates etc) are obtained, and all contractual obligations to suppliers (information provision etc) are delivered. In order to achieve this, we will continue to ensure that our contracts

management database is maintained and that we enforce contractual obligations on suppliers, as appropriate.

➤ ***Managing and enhancing our relationships with all our stakeholders***

In planning key Supply Side transactions and initiatives for the 2004/05 year, we will identify each relevant stakeholder group and consider how best to manage their expectations, inform them of, and involve them in PHARMAC's processes. Mechanisms for ensuring that stakeholders are forewarned of pending PHARMAC initiatives, able to contribute to consultation on relevant issues and are informed of the rationale for decisions made will include regular written communication, liaison with key contacts and face to face meetings as required.

We will continue to build our relationship with the Ministry, in dealing with various issues relevant to pharmaceuticals. We will work with the Ministry to ensure that policy decisions that are consistent with PHARMAC's statutory objectives and functions are implemented in a timely manner with adequate consideration of planning requirements and the ability of the sector to adopt changes.

➤ ***Special Authorities***

As noted above, the Special Authority process is a mechanism that enables particular pharmaceuticals to be targeted at those who are most able to benefit. The Special Authority process enables a prescriber to request government subsidy on certain community pharmaceutical for a particular person. Once approved, the prescriber and the patient are provided a Special Authority number which can provide access to subsidy, additional subsidy or waive certain restrictions otherwise present on a community pharmaceutical.

PHARMAC continues to work jointly with HealthPAC towards the implementation of an electronic application process for Special Authority approvals. We have rolled out the web-browser version to a number of hospitals as well as general practitioners. To date more than 300 applications have been lodged electronically and feedback from users is that the system works well and is preferred over the paper-based system. A fully integrated system is being piloted and we expect that it will be rolled out to general practitioners in July 2004. This integrated system will work through the doctor's own practice software.

We anticipate working closely with HealthPAC over the next few years to ensure that project milestones around uptake of the system are met and help desk services are provided. We will also be working with HealthPAC to ensure that audits of applications occur to test compliance with the system.

3.1.2 Demand Side Initiatives in 2004/05

Encompassed within Strategic Priority One for PHARMAC is promoting the responsible use of pharmaceuticals. This area is addressed by PHARMAC's Demand Side team. How the Demand Side team achieves this is outlined in the diagram below, which details the definition of the team's function, strategies used to achieve the function and targeted projects for each strategy.

(a) Demand Side function, strategies and projects

PHARMAC Demand Side has adopted the “I.A.D.R.I.” (Intent, Approach, Deployment, Results, Improvement) strategic approach to ensure that Demand Side fulfils its legislative function and is focused on continual improvement in the short, medium and long term:

Intent	Legislative function	To promote the responsible use of pharmaceuticals
Approach	7 strategies	Detailed below
Deployment	Projects for each strategy	Detailed below
Results	Fiscal and/or health outcome targets measured through evaluation	Detailed in individual project plans
Improvement	Review/debrief	Quarterly reporting to Board

Legislative function (48(d) H&D Act 2000)

To promote the responsible use of pharmaceuticals

Definition of function

“Responsible use of pharmaceuticals is the use of evidence-based and best practice information to educate and provide information about the optimal use of pharmaceuticals throughout the prescribing continuum, from clinicians’ prescribing through to use by the patient.”

Strategies to achieve function

1. Identifying and undertaking activities in high priority areas - namely therapeutic areas with inappropriate levels of expenditure, volume and/or mix growth, (which may be either too high or too low).
2. Contracting with external parties to promote the responsible use of pharmaceuticals.
3. Supporting Supply Side initiatives.
4. Working with the Quality and Safe Use of Medicines project to improve the Quality Use of Medicines as per the Hospital Pharmaceuticals Strategy.
5. Implementing the Demand Side aspects of the Maori Responsiveness Strategy.
6. Working with the Schedule team to promote clinical best practice through optimising access to the Pharmaceutical Schedule.
7. Promoting PHARMAC.

Projects to implement strategies

- High priority areas*
- Wise use of antibiotics campaign
 - Type two diabetes and self-monitoring of blood glucose
 - Cardiovascular risk awareness campaign
 - Atypical antipsychotics education campaign
- Contracting to promote the responsible use of pharmaceuticals*
- Contracting with BPAC NZ for services to promote the responsible use of pharmaceuticals
- Green Prescription programme

The therapeutic group 1 (TG1) areas targeted by PHARMAC Demand Side initiatives in 2004/05 have an annual expenditure of \$356.06 million (yr end March 2004) and account for 57% of the total pharmaceutical budget. The next level down, therapeutic group 2 (TG2), is the level usually targeted by Demand Side activities. Expenditure in the TG2 areas targeted is \$129.24 million (yr end March 2004.) The table below outlines the TG1 and TG2 areas being targeted in 2004/05 and associated projects for each area.

TG1	TG2	Project
Blood & blood forming	Lipid modifying agents (statins)	Cardiovascular risk awareness, promoting lifestyle modification (diet & exercise) and the role of statins in reducing cardiovascular risk
Nervous system	Atypical antipsychotics	Promote appropriate use of atypical antipsychotics
Infections – agents for systemic use	Antibacterials	“Wise Use of Antibiotics” campaign
Alimentary tract & metabolism	Diabetes management	Diabetes testing – promotion of recommended levels of reasonable and responsible testing among adults with diabetes who are not prescribed insulin and who are not pregnant.

Demand Side projects for 2004/05 broadly fall into four areas:

- eliciting change in the demand for the use of pharmaceuticals in key therapeutic areas (either by clinicians, patients or both);
- implementing IT tools and technologies to encourage informed and responsible prescribing, such as implementing the electronic Special Authority system and investigating the feasibility of producing the Pharmaceutical Schedule on CD on a regular basis.
- contracting external parties to assist in implementing Demand Side initiatives; and
- supporting other PHARMAC activities and strategies such as the Consumer Advisory Committee and Maori Responsiveness Strategy to complement Demand Side activities.

Purpose of Demand Side activities and evaluation of targeted outcomes

Demand Side initiatives aim to have a positive outcome in terms of either fiscal and/or health gains. All major projects must include a clear evaluation component in the form of measurable outputs and/or outcomes. This will ensure that Demand Side management effectiveness can be monitored, and improvements made as required. Evaluation outcomes and/or outputs have been included in each project planned for 2004/05.

Given resource limitations it is necessary to prioritise Demand Side projects and the following criteria are used:

- links to the objectives detailed in the NZ Health Strategy and the Primary Health Care Strategy 2001;
- health outcomes;
- savings (return on investment where measurable);
- implementation cost; and
- level of project difficulty.

Some of the Demand Side projects have a timeframe of longer than 12 months. For example, the CVS campaign being rolled out in 2005 is a continuation and development of the 2003 pilot and 2004 campaign in Auckland and the Central North Island. For projects such as this, and for projects with longer-term health outcome targets, outcomes may be difficult to measure in the short term. Where this is the case, intermediate outcomes and specific outputs have been included. We must be able to show that Demand Side activities are having an impact on the overall volume and mix of pharmaceutical expenditure, and we must be able to show this within a three-year time frame.

(b) Demand Side linkages with health sector strategies

The Demand Side work-plan for 2004/05 is designed to achieve the legislative function of promoting the responsible use of pharmaceuticals. It is linked with key health sector strategies to ensure that programmes are associated with the overall direction desired by the Minister of Health, Ministry of Health, District Health Boards and other associated parties.

The key health strategy objectives being contributed to by Demand Side activities are identified in the following table:

PHARMAC Health Priorities	NZ Maori Health Strategy – He Korowai Oranga 2002	NZ Health Strategy 2000	NZ Primary Care Strategy 2001	Pacific Health Strategy
Diabetes (and renal failure)	✓	✓	<ul style="list-style-type: none"> ▪ Working with local communities and enrolled populations ▪ Coordination of care across service areas ▪ Identification and removal of health inequalities ▪ Developing the primary health care workforce 	
Respiratory disease – asthma, CORD, lung disease	Asthma Reduce smoking	Reduce smoking		
Heart / cardiovascular disease	✓	✓		
Mental Health	✓	✓		
Cancer & Smoking	✓	✓		
Arthritis / Gout	Increase physical activity	Increase physical activity		
Obesity	Reduce obesity / Improve nutrition	Reduce obesity / Improve nutrition		
Oral health	✓	✓		
Population focus – general				

Tamariki Ora / Well child	Child health services / immunisation / hearing	Ensure access to well child checks and immunisation	<ul style="list-style-type: none"> ▪ Offering access to comprehensive services to improve, maintaining and restore peoples health ▪ Continuously improve quality using good information 	✓
Rangatahi / youth health	✓	Reduce rates of suicides and suicide attempts		✓
Pakeke / Adults	Reduce violence in interpersonal relationships, families, schools and communities	Reduce violence in interpersonal relationships, families, schools and communities		
General Population	Injury prevention Increase physical activity	Minimize harm caused by alcohol, illicit drugs		Promoting healthy lifestyles-well-being Primary Health Care Provider/ workforce development Information and research
Disability Support Services	✓			✓
Sexual & reproductive health	✓			

(c) Medium to long-term strategic direction for Demand Side activities

Demand Side has responsibility for PHARMAC's function of promoting the responsible use of pharmaceuticals (section 48(d) NZPHD Act). This has been defined as "the use of evidence-based and best practice information to educate and provide information about the optimal use of pharmaceuticals throughout the prescribing continuum, from clinicians' prescribing through to use by the patient".

To manage the growth in demand for pharmaceuticals, Demand Side management focuses on educating both health professionals and patients about the appropriate use of medicines. This involves utilising proven educational techniques to elicit changes in attitudes, expectations and behaviour of individuals and agencies in the demand chain. PHARMAC has found that it is effective to concurrently target prescribers and consumers with educational messages. As educating health professionals and eliciting public behaviour change takes time, Demand Side management has a medium to long-term strategic focus of three to five years.

PHARMAC will work with DHBs to secure the on-going funding of Demand Side activity. In 2004/05, PHARMAC develop proposals to assist DHBs and as part of the Budget setting process will conclude the range of activity for the 2005/06 year that DHBs will fund.

Health Professional education

PHARMAC works in conjunction with other parties also working in the area of health professional education including university medical and pharmacy schools, professional colleges and organisations to ensure that the latest evidence-based approach is used.

Linking national programmes with local educational outreach is key to maximising the outcome of demand side initiatives. PHARMAC currently works with IPAs, and PHOs, to ensure national programmes are implemented locally and evidence-based messages are consistent across different organisations. To this end, PHARMAC has contracted with BPAC NZ to deliver services to promote the responsible use of pharmaceuticals. The shareholders of this organisation represent the majority of GPs in the country and through the services provided by BPAC NZ PHARMAC will be able to ensure that its nationally run programmes are delivered locally in a timely, coordinated and cost-efficient manner. In recognition of the longer-term strategy required to promote prescriber change, PHARMAC has put in place a three-year contract with BPAC NZ.

PHARMAC recognises the developing role of PHOs and the growing role of various health professionals, such as nurse prescribers, in the prescribing continuum. To this end, PHARMAC is working closely with the Ministry of Health and DHBs to ensure that PHARMAC Demand Side management and the pharmaceutical referred services component of PHO contracts are aligned.

The provision of electronic-based clinical information is growing. PHARMAC is working in conjunction with the Ministry of Health, DHBs and other key stakeholders to ensure activities are coordinated.

Consumer information

PHARMAC uses social marketing techniques in the development and execution of its patient/public education campaigns to promote behavioural change in regard to health. Social marketing uses commercial marketing principles and processes to influence the social and health behaviours of audiences. Examples of this include using mass media to educate the public, as undertaken in:

- the asthma management campaign (launched in 2002/03 and continued in 2003/04); and
- the cardiovascular disease risk awareness programme (piloted in 2002/03 and rolled out in Auckland and the Central North Island in 2004).

PHARMAC currently produces several consumer resources for therapeutic areas where it considers there is a lack of independent, good quality consumer information. Examples of resources PHARMAC has produced include:

- gout management (printed in English, Maori, Samoan, Cook Island, Maori and Tongan);
- diabetes tablets (available in 10 languages);

- “My Medicine Looks Different” (a brochure about tendering and changes in medicine brands);
- several asthma resources including the Asthma Visual Aid;
- cold and flu treatments; and
- cardiovascular risk management information.

PHARMAC also contracts with external organisations to develop patient support material, and where possible utilises existing resources from reputable organisations, such as Asthma and Respiratory Foundation of NZ, National Heart Foundation and SPARC.

PHARMAC works in conjunction with its Consumer Advisory Committee and other consumer groups when developing consumer information.

Collaboration across the sector

Demand Side management works in conjunction with other key stakeholders in the area of pharmaceutical demand. Where appropriate, Demand Side activities are based on New Zealand guidelines and are aligned with activities being undertaken by the Ministry of Health and DHBs. Examples of collaboration include:

- The asthma management campaign which is based on the New Zealand Guidelines Group “Guidelines for the diagnosis and treatment of adult asthma”. This campaign is funded by 21 DHBs, has the support of 11 stakeholder groups and includes resources from several different parties.
- The cardiovascular awareness campaign which has the support of DHBs, is linked with the Ministry of Health’s cardiovascular work programme and the New Zealand Guidelines Group interim consensus statement on the management of dyslipidaemia, and has the support of SPARC and the National Heart Foundation who are both providing resources. PHARMAC has also linked with PHOs in the pilot areas to ensure continuity with local programmes.
- The diabetes project which has involved a wide range of stakeholder groups including the New Zealand Guidelines Group, Diabetes New Zealand, RNZCGP, NZSSD, the Tongan Health Society, Maori Disease State Managers, Diabetes Nurse Specialists Group, the Ministry of Health and the Pharmaceutical Society.

PHARMAC also works closely with the sector on issues relating to direct to consumer advertising (DTCA) as this impacts on pharmaceutical expenditure, volume growth and switching patients from older, less expensive medicines to newer, more costly ones.

Expanding Demand Side role beyond management of demand for subsidised pharmaceuticals

PHARMAC Demand Side management focuses on managing demand for pharmaceuticals that attract a government subsidy. Where there are effective,

evidence-based non-pharmaceutical options, which may help to manage demand and improve health outcomes, PHARMAC will incorporate them into education. For example, information promoting physical activity and dietary advice are integral parts of the cardiovascular awareness campaign.

PHARMAC is increasingly working with DHBs and other agencies on complementary areas of Demand Side management, such as laboratory use, as there are synergies across these areas.

3.1.3 Hospital Purchasing

Strategic Priority 2 recognises PHARMAC's role in national hospital pharmaceutical purchasing. This area is another key funding responsibility area for PHARMAC.

In the time since the Minister of Health's approval of the National Hospital Pharmaceutical Strategy in September 2001, PHARMAC has implemented national procurement contracts for DHB Hospitals that are expected to produce savings of about \$10 million per year (of an approximately \$140 to \$150 million total spend on hospital pharmaceuticals).

Total expenditure by DHBs on pharmaceuticals is difficult to quantify. PHARMAC is provided with purchase volume data from all DHB Hospital Pharmacies, other than when these pharmaceuticals are under national PHARMAC contracts. The data does not include expenditure on the volumes purchased. It is therefore difficult to forecast national expenditure on hospital pharmaceuticals.

During 2004 PHARMAC conducted a review of the National Hospital Pharmaceutical Strategy. The purpose of the review was to evaluate PHARMAC's approach to, and success in, implementing the National Hospital Pharmaceutical Strategy over the previous two years. During the review, feedback was received from DHBs on the success of the Strategy against its stated goals. The review indicated that more than 40% of hospital pharmaceutical expenditure is now under PHARMAC national contracts, and savings of \$10 million per annum had been achieved. It is expected that through continued focus on this strategy there are likely to be further increases in savings and an increase in the percentage of expenditure which is under national contracts.

Following the review, PHARMAC intends to give further consideration to:

- PHARMAC's future involvement in the Quality and Safe Use of Medicines Strategy;
- the future of PHARMAC's Hospital Pharmaceutical Advisory Committee (HPAC);
- options for commercial contracting for hospital supply;
- extension of the Hospital Strategy to include Radiological Contrast Media, Bulk Intravenous Fluids and Recombinant Blood Products; and
- the future of the New Hospital Pharmaceutical Assessment process.

PHARMAC has also established processes for assessing the cost-effectiveness of pharmaceuticals that DHB Hospitals are considering adding to their formularies.

DHB Hospitals are not obliged to follow any recommendations made by PHARMAC. However, the processes are aimed at improving DHB Hospitals' own assessments, encouraging debate about the relative merits and disadvantages of new pharmaceuticals, and enhancing overall decision-making. These processes were reviewed as part of the two year evaluation of the National Hospital Pharmaceutical Strategy and an independent analyst has been contracted to conduct a further detailed analysis of the processes. During 2004/05 consideration will be given as to the future of these processes.

In order to collate national hospital pharmaceutical utilisation data without imposing onerous IT or data coding requirements on DHB Hospitals, PHARMAC has been working on a reporting system which enables DHB Hospital pharmacy sites to report their monthly usage of pharmaceuticals to PHARMAC. A data co-ordinator within PHARMAC then manipulates the data received into a common data format and compiles it into a single database. The project is partly progressed. All DHB Hospitals sites are now regularly reporting usage to PHARMAC. No further input is likely to be required of DHBs, other than the on-going provision of monthly reports (for which programmes have been written and installed to automate the process) and some validation work.

As noted above, during 2004/05 PHARMAC will consider further development of the National Hospital Pharmaceutical Strategy as a result of the two year review undertaken in early 2004. PHARMAC will also consider other areas of DHB Hospital procurement (in pharmaceutical and related areas) where PHARMAC's expertise and experience may benefit the DHBs and result in national savings. This initiative to search for other ways in which PHARMAC can assist DHBs has been recognised as a priority by the addition of Strategic Priority 7 above.

(a) Discretionary Community Supply provisions

Provisions detailed in section H of the Pharmaceutical Schedule and known as Discretionary Community Supply (DCS) and Hospital Exceptional Circumstances (Hospital EC) were introduced in July 2003 to ensure that DHBs could continue to dispense pharmaceuticals for community use and comply with the NZPHD Act. In establishing these provisions PHARMAC recognised that there were some pharmaceuticals, not listed on the Pharmaceutical Schedule, that could be justified for use in the community by hospital out-patients on the grounds of cost-effectiveness (whether generally or in individual cases). Feedback on these provisions was received from DHBs as part of the review of the National Hospital Pharmaceutical Strategy. PHARMAC will be reviewing this feedback and will be undertaking a specific review of the effectiveness of these provisions before the end of 2004.

PHARMAC's challenge for the coming year is to ensure that the DCS list continues to meet the demands of clinicians and patients but does not undermine PHARMAC's existing assessment and funding processes for pharmaceuticals.

(b) Quality Use of Medicines Strategy

PHARMAC in conjunction with HPAC developed and consulted on a Quality Use of Medicines Strategy (QUM Strategy) which focused largely on the secondary care

sector with a more limited focus on the primary/secondary care interface. This Strategy was approved by the PHARMAC Board in February 2002 and PHARMAC staff subsequently sought nominations for positions on the QUM Advisory Committee.

In 2003, a Safe Use of Medicines Group was formed as part of the DHBNZ Chief Executives initiatives. This group contained many of the individuals nominated for the PHARMAC QUM Advisory Committee. Further, it was identified that there was a significant degree of crossover between the two initiatives.

In 2003, a decision was made for two representatives of PHARMAC to be invited to all the Safe Use of Medicines Group meetings. Since that time PHARMAC has played an active role in the Group including assisting with the organisation of the Safe and Quality Use of Medicines Conference held in May 2004.

PHARMAC will further review the future options for the QUM Strategy in 2004.

3.1.4 New Initiatives Strategy

PHARMAC staff have begun a process of seeking information on the current purchasing activities of DHBs in relation to a selected list of pharmaceutical related products and services. PHARMAC anticipates that it could bring an evidence-based evaluation and decision-making approach to procurement of medical products which could deliver value to DHBs. The initial indications are that there is wide variation amongst DHBs in how these purchasing activities are conducted. This may lead to regional rather than national initiatives.

Two initiatives that PHARMAC will be focussing on during 2004/05 are the procurement of the influenza vaccine and the management of the Cancer Basket.

PHARMAC will undertake the procurement of the influenza vaccine on behalf of DHBs for the winter 2005 campaign. The budget for the influenza vaccine and the immunisation benefit will remain with the DHBs. The system for purchase, claiming and criteria for eligible patients will remain unchanged. PHARMAC proposes to issue a Request for Proposals and award a contract before December 2004 for the start of a campaign in April 2005.

It is also proposed that the management of funding for all pharmaceutical cancer treatments be transferred to PHARMAC during the 2004/05 year. All pharmaceutical cancer treatments would be listed in the Pharmaceutical Schedule with associated subsidies. DHB Hospitals would continue to purchase and pay for these cancer treatments as they currently do but would be required to claim for reimbursement via HealthPAC. PHARMAC's indicative pharmaceutical budget would be increased to reflect current spending on pharmaceutical cancer treatments. PHARMAC will be establishing a high level steering group with multi-agency representation to assess this proposal.

3.1.5 Other Key Funding Responsibilities

(a) Exceptional Circumstances

PHARMAC has responsibility for the management of exceptional circumstances (EC) which enables the approval of treatment for patients who have a high need for pharmaceuticals that are not otherwise subsidised and who meet certain criteria.

PHARMAC will manage the operation of the EC Scheme consistent with section 48(b) of the NZPHD Act “in exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the Pharmaceutical Schedule”.

The purpose of the EC Scheme is to provide funding for outpatient medication in circumstances where the provision of a funded medication is appropriate, but the funding is not able to be provided through the Pharmaceutical Schedule. Consistent with the Medicines Act 1981 and the eligibility criteria for the EC Scheme, EC is also used to fund medications that have not received MedSafe approval, for example where supplies are brought into New Zealand under section 29 of the Medicines Act or where a patient is treated for an indication which was not a specified indication in the MedSafe approval.

As noted above, the new DCS and Hospital EC provisions took effect from 1 July 2003. Following the implementation of these provisions, the numbers of applications made under the provisions of Hospital EC was such that an additional staff member was assigned solely to process these applications .

In addition, the costs of the EC Panel substantially increased as the members were now assessing applications on a daily basis. The EC Panel meets two weekly by teleconference to deal with Community EC applications. With the introduction of Hospital EC the Panel members now assess applications on a daily basis, as the turn-around time for Hospital EC applications is 48 hours. The number of Hospital EC applications currently stands at around 250 a month. Where a number of DHBs are applying for a particular pharmaceutical on cost effective grounds under Hospital EC provisions, the EC Panel has recommended a DCS listing. Such a listing would decrease the numbers of Hospital EC applications, and hence lower the EC Panel workload.

(b) National Programmes for High Cost Medicines

As part of managing pharmaceutical expenditure, PHARMAC establishes national programmes and expert panels that encourage the cost effective use of particular high cost pharmaceuticals. These programmes involve targeting the provision of subsidies for certain pharmaceuticals (currently dornase alpha - Pulmozyme, beta-interferon, imiglucerase - Cerezyme, and human growth hormone) to patients meeting defined entry and exit criteria. Decisions on funding are based on published access criteria and are taken by panels of expert clinicians involved in the various areas of treatment. There are currently 15 clinicians appointed to the four panels, and four staff.

Exceptional Circumstances has received a number of applications for funding of several high cost pharmaceuticals used in the treatment of pulmonary hypertension (eg iloprost, bosentan). The numbers of patients with pulmonary hypertension nationally may exceed the limit for approval of funding through Exceptional Circumstances. In addition, as the pharmaceutical costs are high for each patient (up to \$150,000 annually) PHARMAC considers that the establishment of a Pulmonary Hypertension Panel may be effective in ensuring the cost effective use of these high cost pharmaceuticals. PHARMAC will be assessing the need for the establishment of a Pulmonary Hypertension Panel during the course of the year and will take steps to establish such a panel if it considers it necessary.

The high cost medicines panels continue to run smoothly. PHARMAC will continue to assess the most effective way that these panels can deliver.

3.2 Optimising Performance

3.2.1 Working with DHBs

Strategic Priority Three is working with DHBs. PHARMAC has a Relationship Agreement with each DHB which was entered into in January 2002. The DHB Relationship Agreement was motivated by a desire to establish and maintain a constructive and effective working relationship between DHBs and PHARMAC - we are now extending this relationship. During 2003/04 PHARMAC began work with DHBs on formalising processes for the management of rebates. During 2004/05 PHARMAC will continue to work with DHBs on completing an updated Relationship Agreement reflecting new initiatives and the increasing amount of interaction between PHARMAC and DHBs. This will further improve the co-operation and collaboration in the sector and assist in identifying and achieving the mutual goals.

PHARMAC and DHBs have been developing a co-operative relationship since their inception in 2000. PHARMAC extended its working relationship with DHBs during 2002/03 to examining new opportunities as part of the Budget negotiation. In setting the 2003/04 pharmaceutical budget, a new level of co-operation was agreed with the inclusion of disease state and efficiency related activities in our shared work programme. This level of co-operation was built on in setting the 2004/05 budget.

During 2003/04 PHARMAC worked with DHBs on the implementation of changes to Section F of the Pharmaceutical Schedule, to allow the increased use of 'stat' or all-at-once dispensing. This initiative has allowed DHBs to reprioritise spending. It has also enabled DHBs to increase the amount of money available for subsidising pharmaceuticals. PHARMAC will be reviewing all-at-once dispensing by 1 October 2004 as agreed when the policy was implemented.

Relationship building with the DHBs remains a priority area for PHARMAC. Following the success of PHARMAC's efforts to meet with all DHB Board Chairs during 2002/03, PHARMAC intends to visit all DHB Boards during 2004/05 to discuss ways in which PHARMAC can add value to their businesses.

PHARMAC is providing DHBs with monthly expenditure reports, attending meetings and briefings, and liaising with DHBs on issues of common interest, particularly Demand Side initiatives. PHARMAC is also working with DHBs on new activities as

part of the 2004/05 Budget negotiations and as reflected in Strategic Priority 7. During 2004/05, PHARMAC intends to work with DHBs and the Ministry of Health to scope new areas where PHARMAC might be able to provide assistance to DHBs either regionally or nationally. Such areas include PHARMAC assisting with overall health management such as by taking responsibility for vaccine purchasing and negotiating the purchase of other hospital consumables, such as blood and recombinant products.

The relationship between DHBs and PHARMAC is central to the effectiveness of all parties. DHBNZ's Chair continues to be an observer on the PHARMAC Board and PHARMAC representatives attend regular meetings with DHBNZ and consult with them on both Supply Side and Demand Side initiatives. PHARMAC has been developing its relationship with DHBs to ensure that both Supply and Demand Side activities reflect DHB requirements and that DHBs are supportive and engaged in PHARMAC activities. PHARMAC has provided DHBs with copies of project plans and is working to ensure that, where possible, DHBs are contracting with IPAs and PHOs to ensure synergy with these projects. An example of this is the asthma campaign launched in February 2003 which was co-ordinated by PHARMAC, funded with the support of the DHBs and supported by a broad cross section of the medical community, including general practitioners, asthma educators, nurses and pharmacists. PHARMAC is also working with DHBs to ensure that external agencies contracted to undertake pharmaceutical demand services are aligned.

3.2.2 Ensuring all New Zealanders have similar access to Subsidised Pharmaceuticals

Strategic Priority Four is ensuring that all New Zealanders have similar access to subsidised pharmaceuticals. PHARMAC intends to promote the appropriate use of pharmaceuticals by disadvantaged populations, focussing particularly on Maori.

In 2002 PHARMAC released the Maori Responsiveness Strategy following extensive consultation and consideration. This document outlined a programme of action for PHARMAC, which PHARMAC is committed to implementing.

The New Zealand Maori Health Strategy (He Korowai Oranga) recognises a framework for Treaty of Waitangi principles based on partnership, participation and protection. In developing the Maori Responsiveness Strategy PHARMAC has adopted these principles. As well as identifying and working in the key therapeutic areas targeted by He Korowai Oranga, there are also some key objectives outlined in the draft strategy which affect PHARMAC:

- developing partnerships with Maori communities;
- reducing Maori health inequalities;
- improving Maori health information to support effective service delivery and monitoring the achievement of Maori health objectives; and
- ensuring the sector agencies work with Health to take into account the health impact of their activities and to develop initiatives that positively affect whanau health.

In 2001 PHARMAC started developing its Maori Responsiveness Strategy including extensive consultation through a series of hui held throughout New Zealand. The Strategy was approved by the PHARMAC Board in June 2002, and launched at parliament on 10 September 2002.

PHARMAC is implementing the following six key strategies:

- incorporate Maori strategic priorities;
- improve human resources;
- improve ethnicity data collection and analysis;
- improve our performance in negotiating with suppliers and assessing new drug applications;
- improve our performance in informing Maori about available subsidised medicines; and
- improve Maori representation and participation.

PHARMAC has already made significant progress in implementing some of the key strategies including:

- the appointment of Helmut Modlik (Ngati Toa, Ngati Tama, Te Ati Awa) to the PHARMAC Board;
- the appointment of Tony Ruakere (Te Ati Awa) to PTAC;
- the appointment of three Maori members to the Consumer Advisory Committee;
- a series of lectures to PHARMAC staff by prominent Maori;
- the appointment of a Maori Health Manager to take a leadership role in maintaining PHARMAC's responsiveness to Maori and work internally and externally to implement the Strategy; and
- the development of health awareness campaigns specifically targeted at Maori, including the "One Heart Many Lives" campaign and the development of a patient education brochure on gout (identified as a Maori health priority area in the hui).

PHARMAC continues to implement the Maori Responsiveness Strategy as part of its objective to improve access to subsidised medicines for all New Zealanders. Two key areas of the strategy are: improving business planning processes by establishing Maori health priorities and ensuring focus on those priorities; and increasing PHARMAC's responsiveness to Maori health issues by improving data collection processes to explicitly address Maori issues and by improving consultation processes so that the expertise of more Maori providers and health professionals is included. PHARMAC staff are investigating options and models that can be used to improve the use of current ethnicity data. PHARMAC intends to seek advice from external experts in addressing this area.

PHARMAC will continue to look for opportunities to improve the delivery and responsiveness to all New Zealanders in the provision of pharmaceuticals and quality health advice.

3.2.3 Improving Relationships with Stakeholders

Strategic Priority Five is improving relationships with stakeholders.

PHARMAC's focus has moved to building relationships with DHBs based on a programme of successful co-operation. This programme will see PHARMAC enter new areas of activity that have traditionally been outside its core activity. These activities will be designed to improve the efficiency and effectiveness of the sector, and assist patients.

PHARMAC is working with DHBs to ensure increased efficiency in the sector, particularly in the delivery of medicines, and with disease state management activities. In response to calls from pharmacists and patients, PHARMAC has worked with DHBs to implement all-at-once dispensing to address dispensing volumes and dispensing volume growth and improve the quality of the service patients receive. All-at-once dispensing was a positive initiative that allows DHBs to invest in other health services and increase the amount of funding available to subsidise medicines.

Consistent with Strategic Priority 7, PHARMAC plans to extend its operational activities to include new initiatives which assist DHBs. In 2005, PHARMAC intends to assist DHBs in procuring the influenza vaccine for community use. PHARMAC also intends to work with DHBs to transfer the responsibility for managing the funding of all pharmaceutical cancer treatments from DHB Hospitals to PHARMAC under its service budget.

With the use of expenditure data provided by HealthPAC, PHARMAC will continue to provide regular reports on pharmaceutical expenditure to DHBs and continue to assess the form and content of these reports in response to feedback from DHBs. PHARMAC will also continue to meet regularly with its stakeholders in order to achieve closer working relationships and to ensure that the sector works co-operatively on shared goals and priorities. Part of this co-operation has been ensuring that increased sector efficiency is recognised in an improved pharmaceutical budget. This will ensure that access to needed medicines will continue to improve.

Since July 2003, PHARMAC has been sharing business premises with DHB NZ. This has enabled PHARMAC and DHBs to work closer together on issues and co-location has facilitated addressing issues in a more timely manner. It has also had the positive benefit of increased understanding of our respective roles and closer working relationships between staff.

PHARMAC continues to build on its relationships with patients and consumers. Both the Supply Side and Demand Side teams conduct their relationships with patients via communication and interaction with representative groups. During 2003/04 the Supply Side team has focussed particularly on identifying representative groups most likely to be affected by activities during the year ahead and communicating with those groups prior to significant developments. This work will continue in 2004/05. PHARMAC also recognises the value in maintaining regular contact with representative groups beyond the processes triggered by particular developments.

The Consumer Advisory Committee (CAC) continues to play an important role in providing input to PHARMAC's decision making from health consumers' points of view. A review of the work of the Consumer Advisory Committee was undertaken during 2003/04. As a result, there were slight amendments made to the Terms of Reference, but overall the review concluded that the CAC was performing well.

The improving financial situation of PHARMAC should assist to improve its relationship with suppliers and patient groups. PHARMAC will be actively managing these relationships to leverage the benefits of the new environment. PHARMAC will continue with its regular meetings with the pharmaceutical industry. PHARMAC is also involved in public conferences and has developed a stakeholder newsletter.

PHARMAC also has a very important relationship with the Ministry of Health. The Ministry acts as the agent of the Minister in negotiating, communicating and clarifying the Minister's expectations and in monitoring PHARMAC's performance against the Annual Plan and the Crown Funding Agreement. PHARMAC also works closely with HealthPAC and NZHIS (which are divisions of the Ministry) in carrying out its statutory objectives.

PHARMAC's performance in a number of areas is dependent upon receiving data from HealthPAC and upon HealthPAC's assistance in implementing new initiatives. The performance of PHARMAC therefore depends upon HealthPAC meeting agreed deliverables in a timely manner. Data received from HealthPAC is stored on PHARMAC's behalf within the Pharmhouse data warehouse by NZHIS. PHARMAC's continued timely access to this data and involvement in the processes surrounding the structure and governance of the data warehouses are critical to PHARMAC's ongoing performance.

PHARMAC is developing a Memorandum of Understanding with the Ministry of Health regarding the relationship between PHARMAC, HealthPAC and NZHIS. This document will replace the service level agreements which PHARMAC had with each party and will set out the expectations of each party in dealing with the other.

HealthPAC has indicated its intention to charge PHARMAC for the costs of implementing proposals that necessitate changes to HealthPAC's systems. However, PHARMAC and HealthPAC are still working together to identify an appropriate basis on which to charge for changes and to define what will constitute a change. Until this work is complete, PHARMAC is not able to accurately estimate the impact of HealthPAC's decision to charge. These costs have not been provided for in PHARMAC's operating budget for 2004/05. To the extent that PHARMAC and the Ministry agree that PHARMAC should bear these costs, PHARMAC and the Ministry will also need to agree on how these costs will be funded.

During 2004/05 PHARMAC will also work more closely with other Governmental agencies to assist implementation of the Government's objectives including offering assistance with any Free Trade Agreement with the United States of America, and with reviews of the wider health or commercial environment in New Zealand. PHARMAC will also consider whether there are opportunities for a closer working relationship with ACC.

3.2.4 Developing PHARMAC's Internal Capacity

Strategic Priority Six is developing PHARMAC's internal capacity.

PHARMAC has identified a number of strategic initiatives, some of which will enhance its internal processes including a review of its information management systems and technology.

PHARMAC will be implementing a new system to allow the Pharmaceutical Schedule to be printed directly from PHARMAC's electronic database. PHARMAC has been working with HealthPAC to implement system changes which are necessary in order to progress this project.

PHARMAC continues to monitor staffing levels to ensure that the most appropriate mix and number of skilled staff are available to meet the needs of PHARMAC's business. Growth in the organisation over recent years forced PHARMAC to relocate to a new site 2003. The relocation went smoothly and the new location has allowed PHARMAC to co-locate with DHBNZ. The new premises have also allowed for more meeting space, so that it is easier for PHARMAC to meet with external parties.

Communications Strategy

PHARMAC has improved its media coverage over the last year. Our communications focus will now centre on improving the relationships PHARMAC has with key agencies, especially DHBs. This will be built on mutual success in implementing initiatives. The Hospital Purchasing Strategy and Dispensing Volumes Strategy are the first to be initiated. The closer PHARMAC can work with DHBs on initiatives, the more effective its communications with the sector will become.

PHARMAC has continued to improve its website, including an on-line notification system when PHARMAC is consulting on a proposal. This means that interested parties receive an email advising of a consultation and saves people having to check the website randomly.

PHARMAC has also begun producing a quarterly newsletter for stakeholders, InPHARMation. This newsletter is designed to provide an update on recent developments with pharmaceuticals and on PHARMAC's activities. The first edition of this newsletter was sent to stakeholders in February 2003. PHARMAC expects to continue to produce this newsletter during 2004/05. PHARMAC will also continue to report to DHBs on a monthly basis with information in relation to pharmaceutical expenditure.

4 RISK ANALYSIS

The pace of sector changes and trends in the environment outlined above contribute to the degree and nature of risk that PHARMAC will face in the 2004/05 year.

PHARMAC has a well developed risk management system which provides for risks to be captured as they arise, documented, reviewed and reported to the PHARMC Board and Minister of Health.

The key risks facing PHARMAC (identified with reference to PHARMAC's strategic priorities) and the mechanisms PHARMAC has in place to mitigate these risks are outlined in the table below.

What could happen?	Control mechanism
<i>Strategic Priority 1 – Comprehensive management of pharmaceutical expenditure and use</i>	
Growth of pharmaceuticals in areas of low therapeutic value.	Continual review of Pharmaceutical Schedule and influencing prescriber behaviour through demand side strategies.
Vulnerability to currency fluctuations, given that major pharmaceutical companies are focussed offshore.	Contracting where possible in \$NZ.
General legal challenges to contracting policies.	Robust and transparent systems and processes in place and complied with by staff.
Decline in pharmaceutical expenditure data access or integrity.	Monitoring expenditure data and working with the Ministry to ensure continued access and control over such data.
Loss of budget management and holding by IPAs without the establishment of similar contracts with PHOs	PHARMAC is represented on two groups developing quality and resource management models for PHOs.
Direct to Consumer Advertising (DTCA) – delays in developing regulatory framework following the DTCA review in May 2001 could result in increased demand for subsidised drugs and increased pressure to list non-subsidised drugs.	PHARMAC supports the Minister's position and the Government policy on this issue. PHARMAC is providing resources or advice on this issue if requested to do so by the Minister or the Ministry.
<i>Strategic Priority 2 – Hospital Pharmaceutical purchasing</i>	
Lack of data to assess hospital tender bids and monitor contracts – difficulty of forecasting national expenditure on hospital pharmaceuticals.	Continuing establishment of an in-house hospital pharmaceutical dataset and working with DHBs to improve data without imposing onerous requirements.
Ensuring Discretionary Community Supply list meets the demands of clinicians and patients but doesn't undermine assessment and funding processes.	Seeking feedback from DHBs and undertaking a review of the DCS provisions

<i>Strategic Priority 4 – Improving Maori utilisation of pharmaceuticals</i>	
Measuring and monitoring whether Maori are accessing and receiving subsidised medications on an on-going basis is difficult because ethnicity is not recorded on prescription forms.	Implementing PHARMAC's Maori Responsiveness Strategy including working to improve the Maori health information base by advocating for collection of relevant data and by working with providers in high Maori population areas to share information on prescribing and hospitalisation patterns.
<i>Strategic Priority 5 – Improving Relationships with Stakeholders</i>	
Campaigns by the pharmaceutical industry to challenge PHARMAC's policies and procedures could distract focus from PHARMAC's core functions or, if successful, could impact on the way in which PHARMAC manages its core business.	Actively working with a range of stakeholders to increase understanding of PHARMAC's functions and to avoid challenges.
<i>Strategic Priority 6 – Developing PHARMAC's internal capacity</i>	
Transitional structural change issues may impact upon PHARMAC's management of its core business.	Proactive development of relationships with new entities in the health sector. Prioritisation of workloads.
<i>Strategic Priority 7 – New Initiatives</i>	
Negative impact on PHARMAC's core business through extension into other areas.	Stakeholder support and full information gathering from a number of sources before any decision is made to extend PHARMAC's work in other areas.

5 FINANCIAL INFORMATION

5.1 Service Budget Performance 2004/05

DHBs and PHARMAC have agreed to recommend that the Community Pharmaceutical Budget for the next three years be initially set as follows:

Year ending 30 June (\$ million)	2005	2006	2007
Underlying Pharmaceutical Budget	517.3	519.0	529.7
Key Policy Impacts - Stat dispensing	16.7	17.1	17.4
- Access policies	31.0	31.9	31.9
Three year funding path	565	568	579

The proposed budget is sufficient to allow for investment in new technologies for each of the next three years. PHARMAC considers that this will ensure that New Zealanders will continue to benefit from increased access to important new medicines. It demonstrates the Government's commitment to funding innovative pharmaceuticals.

Adjustments to the initial budget will be required during the period so as to allow for changes in policies and market behaviour including the following.

- a recent decision that will increase expected rebates in 2004/05 and the out-years;
- potential impact of changes to the way medicines are approved;
- further changes in co-payments for other age groups; and
- the funding of cancer treatments through the Pharmaceutical Schedule.

Overall, we anticipate the effect of taking these issues into account in our July 04 Forecast Update will be to leave the net position (i.e. "Expected Drug Cost") largely unchanged.

PHARMAC and DHBs are currently proposing the Notional Community Pharmaceutical budget for 2004/05 be set at \$565 million. In addition, a three year funding path is proposed that includes budgeting for \$568 million in 2005/06 and \$579 million in 2006/07. If this is accepted, current forecasts indicate that PHARMAC will be able to make significant investments in new pharmaceuticals this year and in the out-years covered by the funding path.

The Notional Community Pharmaceutical budget will be reviewed quarterly throughout the year and amended in the light of changes in the external policy environment and our estimated impact of such changes.

Operating Budget Financial And Ownership Information

5.2.1 Statement of Accounting Policies

(a) Reporting entity

PHARMAC is a body corporate owned by the Crown with perpetual succession and is responsible for securing for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. It has sole responsibility for managing the Pharmaceutical Schedule.

Forecast financial statements in this document have been prepared in accordance with section 67(1) of the NZPHD Act 2000 and the Public Finance Act 1989.

(b) Measurement system

The general accounting policies, recognised as appropriate for the measurement and reporting of financial performance and position on a historical cost basis, have been followed in the preparation of the projected financial statements.

(c) Accounting policies

The following particular accounting policies, which materially affect the measurement of results and financial position, have been applied.

➤ Valuation of assets

(i) Fixed Assets

Fixed Assets are valued at cost less accumulated depreciation.

(ii) Accounts Receivable

Accounts receivable are valued at net realisable value.

➤ Depreciation

Depreciation of fixed assets is calculated using the straight line method to allocate the historical cost over the estimated useful life of each asset.

Major depreciation periods are:

Office equipment	2.5 - 5 years
EDP equipment	2.5 years
Furniture and fittings	5 years
Leasehold improvements	5 years

➤ **Revenue recognition**

Revenue received from the Crown to cover operating costs is recognised as the revenue falls due.

➤ **Goods and Services Tax (GST)**

All amounts shown are exclusive of goods and services tax, with the exception of debtors and creditors, which are shown GST inclusive.

➤ **Taxation**

For the purposes of the Inland Revenue Acts, PHARMAC is a “public authority” as stated in clause 32(1) of Schedule 6 of the NZPHD Act 2000.

➤ **Financial instruments**

There are no financial instruments that expose PHARMAC to foreign exchange risk or off balance sheet risks, although PHARMAC has entered into contracts with pharmaceutical suppliers that provide for limited variations in price according to exchange rate fluctuations.

All financial instruments, including bank accounts, accounts receivable and accounts payable are disclosed at their fair value. Revenue and expenses, in relation to the financial instruments, are recognised in the Statement of Financial Performance.

➤ **Employment entitlements**

PHARMAC’s liability for annual leave has been provided for and has been calculated on an entitlement basis at current rates of pay.

➤ **Budgeted figures**

The 2004/05 budget figures, and 2005/06 and 2006/07 forecast figures have been prepared in accordance with generally accepted accounting policies adopted by the Board.

➤ **Leases**

PHARMAC sub leases office premises. As all the risks of ownership are retained by the lessor, these leases are classified as operating leases. Operating leases are expensed in the period in which they are incurred.

➤ **Changes in accounting policies**

There are no changes in accounting policies. All accounting policies have been applied on a consistent basis.

5.2.2 Projected Statement of Financial Performance

	For the period of 1 July 2004 to 30 June 2005 \$000 (GST excl)	For the period of 1 July 2005 to 30 June 2006 \$000 (GST excl)	For the period of 1 July 2006 to 30 June 2007 \$000 (GST excl)
Revenue			
Crown:			
Operating ^{1 2}	8,060	8,690	9,128
Responsible use of pharmaceuticals	2,895	3,040	3,192
Interest received	190	190	190
Total Revenue	11,145	11,920	12,510
Operating Expenditure			
Operating costs	3,617	3,797	4,013
Salaries and related costs	3,572	3,751	3,938
Audit fees	15	17	19
Directors fees	121	121	121
Depreciation	280	280	280
Rentals and leases	288	288	288
High cost medicines	412	433	454
Responsible use of pharmaceuticals	4,570	3,040	3,192
Total Expenditure	12,875	11,727	12,305
Net surplus/(deficit)	(1,730)³	193	205

Note: The above statement should be read in conjunction with the accounting policies on pages 41 and 42.

¹ As noted in above, PHARMAC is not currently funded for systems development changes that HealthPAC has indicated it intends to charge. If it is agreed between PHARMAC and the Ministry that PHARMAC will pay these charges, the Ministry and PHARMAC will need to agree on a mechanism for funding the charges.

² PHARMAC is funded for High Cost Medicines within its operating budget.

³ PHARMAC has forecast a deficit of \$1,730,000 (excluding GST) for the 2004/05 year. This deficit will be funded by PHARMAC from equity reserves. This will reduce PHARMAC's equity reserves to an appropriate level and contribute to managing financial pressures in the health sector.

5.2.3 Projected Statement of Financial Position

	At 30 June 2005 \$000 (GST excl)	At 30 June 2006 \$000 (GST excl)	At 30 June 2007 \$000 (GST excl)
<i>PUBLIC EQUITY</i>			
Retained Earnings & Reserves	7,406	7,599	7,804
TOTAL PUBLIC EQUITY	7,406	7,599	7,804
Represented by:			
<i>Current Assets</i>			
Cash and bank	10,373	10,373	10,373
Receivables and prepayments	181	139	242
Total current assets	10,554	10,512	10,615
<i>Non-current assets</i>			
Fixed assets	400	400	400
Total non-current assets	400	400	400
<i>Total assets</i>	10,954	10,912	11,015
<i>Current liabilities</i>			
Payables	3,548	3,313	3,211
Total current liabilities	3,548	3,313	3,211
NET ASSETS	7,406	7,599	7,804

Note: The above statement should be read in conjunction with the accounting policies on pages 41 and 42.

5.2.4 Projected Cash Flow Statement

	For the period of 1 July 2004 to 30 June 2005 \$000 (GST incl)	For the period of 1 July 2005 to 30 June 2006 \$000 (GST incl)	For the period of 1 July 2006 to 30 June 2007 \$000 (GST incl)
Cash flows – Operating activities			
Cash was provided from:			
- Ministry of Health	12,324	12,941	13,588
- Interest	190	190	190
	12,514	13,131	13,778
Cash was disbursed to:			
- Cash outflow to suppliers and employees	(13,600)	(12,470)	(13,117)
- Net GST	(364)	(381)	(381)
	(13,964)	(12,851)	(13,498)
Net cash flow from operating activities	(1,450)	280	280
Cash flows – Investing activities			
Cash was disbursed to:			
- Purchase of fixed assets	(280)	(280)	(280)
Net cash flow from investing activities	(280)	(280)	(280)
Cash flows – Financing activities			
Net cash flow from financing activities	0	0	0
Net increase/(decrease) in cash held	(1,730)	0	0
Add opening cash brought forward	12,103	10,373	10,373
Closing cash balance	10,373	10,373	10,373

Note: The above statement should be read in conjunction with the accounting policies on pages 41 and 42.

5.2.5 Projected Movement of Equity

	2004 / 2005 \$000 (GST excl)	2005 / 2006 \$000 (GST excl)	2006 / 2007 \$000 (GST excl)
Public equity at the beginning of the period	9,136	7,406	7,599
Net surplus/(deficit)	(1,730)	193	203
Public equity as at the end of the period	7,406	7,599	7,804

Note: The above statement should be read in conjunction with the accounting policies on pages 41 and 42.

5.2.6 Reconciliation of Net Surplus to Cash Flow from Operating Activities

2004 / 2005	2005 / 2006	2006 / 2007
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	\$000 (GST excl)	\$000 (GST excl)	\$000 (GST excl)
Net operating surplus (deficit)	(1,730)	193	205
<i>Add non-cash items:</i>			
Depreciation	280	280	280
Total non-cash items	280	280	280
<i>Add/(less) working capital movements:</i>			
Decrease (increase) in receivables	(56)	42	(103)
Increase (decrease) in payables	140	(235)	(102)
Working Capital Movement – net	84	(193)	(205)
Net cash flow from operating activities	(1,366)	280	280

Note: The above statement should be read in conjunction with the accounting policies on pages 41 and 42.

5.2.7 Key Assumptions

- The operating budget has been based upon the continuation of PHARMAC's existing level of activity, provision for new activities, future work plans and estimated costs.
- Demand Side budget is based on estimated future activity.

5.2.8 Actual results may differ from Forecast

This summarised financial information is forward looking and based on prudent assumptions which may or may not eventuate. The financial forecasts are dependent on the outcome of funding negotiations for the out-years. Accordingly, the actual financial performance, financial position and cash flows are likely to vary from the projected information presented.

6 INFORMATION AND PERFORMANCE REPORTING

6.1 Reporting requirements

6.1.1 Formal Monthly Reports

PHARMAC will provide the Minister and the Director-General of Health with a monthly report by the 20th working day of the following month covering, at a minimum:

- (a) pharmaceutical subsidy expenditure and rebates compared with budget and revised forecasts of expenditure and rebates when appropriate;
- (b) major Schedule decisions;
- (c) significant issues or developments that the Minister or Ministry should be aware of;
- (d) any potential non-performance against the Crown Funding Agreement;
- (e) PHARMAC's operational financial performance showing:
 - (i) Year to date: actual, budget, variance (\$), variance (%), with commentary to explain significant variances;
 - (ii) Year to date financial performance;
 - (iii) Year to date financial position;
 - (iv) Year end forecast; and
 - (v) Year end budget.

6.1.2 Formal Quarterly Reports

PHARMAC will provide a quarterly report to the Ministry of Health by the end of the 20th working day of the month following the end of each quarter (ie October, January, April and July) comprising:

- (a) PHARMAC's performance against all performance measures contained in Schedule B of this Agreement that fell due in the previous quarter. PHARMAC may also outline progress made towards achievement of significant milestones due in later quarters; and
- (b) an update on price, volume, mix and expenditure indices;
- (c) a statement of cashflows for the immediately preceding quarter; and
- (d) a report on PHARMAC's use of the Legal Risk Fund, including: litigation expenditure; confirmation that PHARMAC has used the monies in the Fund in accordance with the model set out in the Minister's letter of 6 November 2003; and, following the end of each financial year, identification of any unspent operating litigation budget added to the Fund.

6.1.3 Informal Reports

In addition to the formal reports the Board, will, at any time necessary:

- alert the Minister of Health and the Ministry of Health to any emerging factors that PHARMAC is aware of that could preclude the achievement of any expectation set out in the Crown Funding Agreement; and
- inform the Minister and the Ministry of any issue likely to be of significance to the Minister of Health.

6.1.4 Reports to Parliament

PHARMAC will prepare a Statement of Intent for 2005/06 and Annual Report for July 2005 to June 2006.

The content and timing of the production of these documents shall comply with the requirements of the NZPHD Act 2000 and the PF Act 1989.

6.1.5 Ministerial Support

On request, PHARMAC will provide:

- the Ministry with information that will enable the Ministry to prepare Ministerial briefings and draft speech notes in writing and, where practicable, in an agreed form; and
- the Ministry with information (in writing and in an agreed form) that will enable the relevant Minister to respond to:
 - (i) Parliamentary questions;
 - (ii) routine Ministerial correspondence; and
 - (iii) select committee inquiries; and
- the Ministry with information relating to PHARMAC's activities that enables the Ministry to conduct special reviews and audits, which may be carried out as often as the Crown reasonably believes those reviews and audits are necessary.

6.2 Performance Indicators and Targets

6.2.1 Purchase Objectives Output: Management of Pharmaceutical Expenditure

As set out in the Crown Funding Agreement, PHARMAC has one output class “securing the best achievable health outcomes from pharmaceutical treatment, within the funding provided”. There are five business activities within this one output class.

The five business activities include, but are not limited to:

- 1) Management of Community Pharmaceutical Expenditure, including:
 - management of community pharmaceutical expenditure on behalf of DHBs;
 - management of the Pharmaceutical Schedule to determine eligibility for access to subsidised pharmaceuticals;
 - operation of the Exceptional Circumstances Scheme; and
 - management of national programmes for High Cost Pharmaceuticals.

This activity contributes to Strategic Priority 1.

- 2) Promotion of the Responsible Use of Pharmaceuticals, including:
 - Demand Side projects;
 - referred services contracts; and
 - support of the Consumer Advisory Committee.

This activity contributes to Strategic Priority 1.

- 3) Management of Hospital Pharmaceutical Purchasing, including:
 - negotiating supply contracts for some hospital pharmaceuticals on behalf of DHBs;
 - establishing an elective national process for assessing applications to fund new pharmaceuticals in hospitals; and
 - developing a Quality Use of Medicines Strategy for hospital pharmaceuticals in consultation with DHBs.

This activity contributes to Strategic Priority 2.

- 4) Research Fund:
 - establish a mechanism with the Health Research Council and DHBs to fund pharmaceutical related research.

This activity contributes to Strategic Priority 3.

- 5) Assist DHBs on New Initiatives:
 - procure the influenza vaccine for 2005; and
 - assume responsibility for the management of expenditure for pharmaceutical cancer treatments.

This activity contributes to Strategic Priority 7.

PHARMAC has sole responsibility for maintaining and managing the Pharmaceutical Schedule, which applies consistently throughout New Zealand.

Activity One: Management of Community Pharmaceutical Expenditure

	Expectation	Deliverable	Target Date
1.1	PHARMAC will manage expenditure on community pharmaceuticals within the levels agreed in the Crown Funding Agreement.	<p>Subject to deliverable 1.2 below, PHARMAC will maintain expenditure on subsidised community pharmaceuticals for the year ending 30 June 2005 within \$565 million (excl GST), after deduction of rebates from pharmaceutical suppliers.</p> <p>Subject to deliverable 1.2 below, quarterly pharmaceutical expenditure targets on a cumulative basis, (excluding GST) before the deduction of rebates are: Quarter One \$164 million Quarter Two \$333 million Quarter Three \$494 million Quarter Four \$664 million</p>	30 September 2004 31 December 2004 31 March 2005 30 June 2005
1.2	PHARMAC will review the expenditure target for the following quarters on a quarterly basis.	<p>PHARMAC will review the quarterly pharmaceutical expenditure targets phasing set out in deliverable 1.1 above and if appropriate propose amendments to those deliverables to DHBs and the Ministry.</p> <p>PHARMAC in discussion with DHBs, will review the spend target mid way through the year, and recommend any adjustments to the Minister</p>	30 September 2004 31 December 2004 31 March 2005 31 December 2004
1.3	PHARMAC will forecast pharmaceutical expenditure.	PHARMAC will provide the Ministry of Health with a 1-3 year forecast of pharmaceutical expenditure.	31 December 2004
1.4	PHARMAC will monitor pharmaceutical expenditure in the community against forecast.	Any potential deviation from the forecasts will be promptly notified to the Ministry.	Identified in monthly reports if required.

Activity Two: Promoting the Responsible Use of Pharmaceuticals

As noted above, this requires the development of relationships with key stakeholders and strategies to ensure appropriate prescribing behaviour and usage of pharmaceuticals.

	Expectation	Deliverable	Target date
2.1	PHARMAC will promote the responsible use of pharmaceuticals by aiming to influence the volume and mix of medicines prescribed.	<p>An evaluation report on the Cardiovascular Management Campaign to be provided to the Ministry.</p> <p>PHARMAC will undertake the "Wise Use of Antibiotics" campaign during the winter of 2004. A report evaluating the campaign to be provided to the Ministry.</p> <p>PHARMAC will provide Pharmhouse data to the Ministry demonstrating the results of the Diabetes Test Strip Project.</p> <p>PHARMAC will provide Pharmhouse data to the Ministry demonstrating the results of the Atypical Antipsychotics project.</p>	<p>28 February 2005</p> <p>31 December 2005</p> <p>30 April 2005</p> <p>30 June 2005</p>
2.2	PHARMAC will contract with external parties which promote the responsible use of pharmaceuticals.	<p>PHARMAC will contract with BPAC New Zealand to deliver services in 2004/05. Quarterly reports will be provided to PHARMAC by the partnership by the 20th of the month following each quarter, detailing whether it has met the output and outcome targets agreed to in the contract and service plan.</p> <p>PHARMAC will contract for the delivery of the Green Prescription programme in 2004/05. Quarterly reports will be provided to PHARMAC by SPARC by the 20th of the month following each quarter detailing whether the programme has met agreed targets in the contract.</p>	BPAC and SPARC to meet quarterly performance targets specified in funding contracts with PHARMAC.
2.3	PHARMAC will promote the responsible use of pharmaceuticals by making the Pharmaceutical Schedule readily available to GPs.	PHARMAC will undertake an evaluation of a pilot of the Schedule on CD.	The evaluation will be completed by 30 June 2005.

Activity Three: Management of Hospital Pharmaceutical Purchasing

PHARMAC has been authorised to manage the purchasing of hospital pharmaceuticals on behalf of DHBs. In carrying out the Hospital Purchasing function PHARMAC either has, or will, address at the appropriate time, at a minimum, the following factors:

- (a) maintenance and updating of the hospital pharmaceutical strategy as required;
- (b) consulting and communicating with DHBs and other interested parties as PHARMAC considers appropriate;
- (c) amending PHARMAC planning, funding and policy documents to the extent appropriate;
- (d) compiling and analysing information from DHBs on pharmaceutical volumes, expenditure, and contractual arrangements;
- (e) adjusting the Pharmaceutical Schedule as necessary;
- (f) carrying out purchasing on behalf of DHBs;
- (g) calculation and payment to DHB Hospitals of rebates and/or financial compensation payable under national contracts for hospital pharmaceuticals;
- (h) ensuring the hospital pharmaceutical database is maintained and appropriate updates are made and using this data to assist in making future decisions regarding hospital pharmaceutical purchasing;
- (i) monitoring DHB compliance with restricted brand contracts containing Hospital Supply Status (HSS) provisions for hospital pharmaceuticals annually; and
- (j) operating the discretionary community supply (DCS) and Hospital exceptional circumstances (EC) schemes. These two programmes ensure that patients who are discharged into the community can continue on the treatments that were commenced whilst they were inpatients.

The performance measures for this activity in 2004/05 are given in the following table.

	Expectation	Deliverable	Target Date
3.1	PHARMAC will collect hospital pharmaceutical utilisation data to monitor national contracts.	Provide a report about DHB compliance with restricted brand contracts to DHBs and the supplier annually and complete any actions required to be taken.	By 1 November 2004
		Rebates under hospital pharmaceutical contracts calculated and distributed to DHBs.	Within six months of the end of each rebate period whether quarterly, six-monthly or annually.
3.2	Ensure that the Discretionary Community Supply System is effective.	Review the Hospital DCS system.	31 December 2004

	Expectation	Deliverable	Target Date
3.3	PHARMAC will promote and further develop processes for assessing new pharmaceutical technology in hospitals.	6-8 Cost Utility Analyses completed and shared with DHBs.	Three by 31 December 2004. Four to six by 30 June 2005.
3.4	PHARMAC will consider its future involvement in the promotion of the Quality Use of Medicines and Safe Use of Medicines in the hospital setting.	The Board will decide the role PHARMAC will play in the Quality Use of Medicines and Safe Use of Medicines in the hospital setting.	30 September 2004.
3.5	As part of the Hospital Strategy, PHARMAC will examine options to include radiological contrast media.	PHARMAC will provide information to DHB CEOs that identifies option(s) for establishing a competitive process, contracting system and inclusion in the Pharmaceutical Schedule. If agreed, PHARMAC will develop a process for DHB data provision to ensure compliance with any resulting agreement. Implementation of agreed process.	Consultation on option(s) will be complete by 31 October 2004. 31 May 2005 Commencing by 31 May 2005.
3.6	As part of the Hospital Strategy, PHARMAC will examine options to include bulk intravenous fluids.	PHARMAC will provide information to DHB CEOs that identifies option(s) for establishing a competitive process, contracting system and inclusion in the Pharmaceutical Schedule. If agreed, PHARMAC will develop a process for DHB data provision to ensure compliance with any resulting agreement. Implementation of agreed process.	Consultation on option(s) will be complete by 31 October 2004. 31 May 2005. Commencing by 31 May 2005
3.7	PHARMAC will extend the Hospital Strategy to include recombinant blood products	PHARMAC will work with the New Zealand Blood Service (NZBS), the Ministry of Health, DHBNZ and the DHB Working group on the strategy and future contracting for supply of recombinant blood products. PHARMAC will present an options paper to the PHARMAC Board subject to an outcome being agreed by NZBS, MOH and DHBNZ.	31 December 2004
3.8	Review of the Hospital Pharmaceutical Advisory Committee (HPAC).	Review the structure and function of HPAC.	31 December 2004

Activity Four: Research Fund

PHARMAC has been authorised to establish a fund that will allow the Crown to fund independent pharmaceutical related health research.

The performance measures for this activity in 2004/05 are given in the following table.

	Expectation	Deliverable	Target Date
4.1	PHARMAC will develop a fund that will be used to fund independent health research in partnership with the Health Research Council.	Work with DHBs to establish a fund and get DHBs' approval for a research budget. PHARMAC will present a budget proposal to the Minister of Health.	31 December 2004 31 May 2005

Activity Five: Assist DHBs on New Initiatives

PHARMAC has been authorised to procure the influenza vaccine on behalf of District Health Boards, and over time assume responsibility for the management of both community and hospital cancer treatments.

The performance measures for this activity in 2004/05 are given in the following table.

	Expectation	Deliverable	Target Date
5.1	PHARMAC will assist DHBs by procuring the influenza vaccine.	Issue a Request for Proposals. Evaluating proposals, negotiating with submitter(s) of one or more preferred proposals. Consulting on a provisional agreement and PHARMAC's Board or Chief Executive considering this provisional agreement. Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is October/November 2004 for the March 2005 campaign.	31 July 2004 31 August 2004 30 September 2004
5.2	PHARMAC will assist DHBs by managing the expenditure of Pharmaceutical Cancer Treatments.	Review Oncology basket, develop and consult on Pharmaceutical Schedule Rules. Develop Budget setting process. Consult with suppliers and publish new rules. Implementation.	31 October 2004 30 November 2004 31 March 2005 1 July 2005

6.2.2 : Ownership Performance

PHARMAC will deliver the ownership performance in Section Three of its Funding Agreement and in particular will meet the following performance measures.

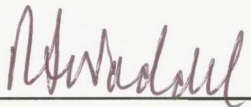
	Expectation	Deliverable	Target Date
6.1	PHARMAC works effectively with DHBs	<p>Complete strategic initiatives to assist DHBs, and develop appropriate reporting mechanisms. Six monthly reporting to DHB representatives.</p> <p>Relates to initiatives 3.5 - 3.7 and 5.1 – 5.2.</p> <p>Review the implementation of all-at-once dispensing, as agreed when the policy was implemented.</p>	By 1 October 2004
6.2	<p>PHARMAC will ensure that all New Zealanders have similar access to subsidised pharmaceuticals by implementing its Maori Responsiveness Strategy.</p> <p>Report to the PHARMAC Board quarterly on progress against implementation of initiatives.</p>	<p>PROJECT I Develop patient and whanau education resources dealing with the use of medications – (linked to project II train the trainer hui).</p> <p>PROJECT II Train the trainer hui to be held for:</p> <ul style="list-style-type: none"> ▪ Maori Disease State Management Nurses; ▪ Maori Community Health Workers; and ▪ Maori Community Nurses. <p>PROJECT III</p> <ul style="list-style-type: none"> ▪ Maori provider and stakeholder hui to build relationships and understanding of PHARMAC and subsidised medicines and the demand side campaigns <p>Analyse options and report to PHARMAC Board on the capture and use of information that will assist in ensuring consistent access to subsidised medicines for all New Zealanders. Specifically looking at:</p> <ul style="list-style-type: none"> ▪ Nationwide surveillance ▪ Sentinel surveillance ▪ Discrete epidemiological cross sectional surveys 	<p>Project I 30 March 2005</p> <p>Project II 31 May 2005</p> <p>Project III 30 June 2005</p>

	Expectation	Deliverable	Target Date
6.3	PHARMAC will consider input from a consumer or patient point of view.	PHARMAC with the assistance of the Consumer Advisory Committee will undertake a project to update the lists of groups, parties and individuals that PHARMAC consults with.	31 March 2005
6.4	PHARMAC will develop with DHBs an ongoing mechanism for funding of Demand Side activity.	Develop, consult and get agreement for the on-going funding of Demand Side Initiatives with DHBs. DHB financial support for Demand Side in 2005/06 agreed with DHBs.	Signal this to DHBs in July 2004 Consult on process 30 November 2004 31 March 2005

7 AGREEMENT AND SIGNATURES

This Annual Plan for 2004/05 is put forward for approval by the Hon Annette King, Minister of Health.

signed for and on behalf of the
PHARMACEUTICAL MANAGEMENT AGENCY

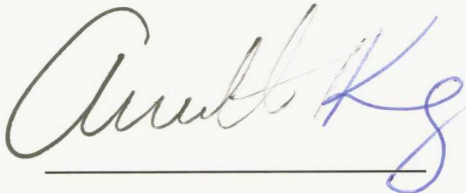


Richard Waddel
Chairman
PHARMAC

DATE: 29 July 2004

This Annual Plan is approved

Yes / No



Hon Annette Faye King
Minister of Health

DATE: 15/8/04